IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-OP-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804

EXPERT REPORT OF DR. ANUPAM B. JENA, MD, PhD

May 10, 2019

TABLE OF CONTENTS

I. INTRODUCTION

A. Qualifications

1. I am the Ruth L. Newhouse Associate Professor of Health Care Policy and Medicine at Harvard Medical School and a physician in the Department of Medicine at Massachusetts General Hospital, the largest affiliated teaching hospital of Harvard Medical School. As a physician, I work as an Internal Medicine Specialist treating patients in the hospital. I treat a wide variety of acute general medical conditions, including cardiovascular diseases such as heart attacks and heart failure; infectious diseases like pneumonia and sepsis; acute complications of liver and kidney disease; complications of substance abuse, including opioids and alcohol; and many other conditions that require inpatient medical care. In my clinical practice I prescribe a broad range of pharmacologic and other therapies and am familiar with how clinical decisions are made regarding treatment. In particular, I routinely prescribe prescription opioid and other analgesic medications to patients with pain in the inpatient setting and, as a prescriber of these medications, I am intimately familiar with the patients who require these treatments, the treatments' indications and contraindications, and how prescribing decisions are made. I also treat patients with opioid use disorder and am familiar with the treatments that are used and, importantly, how this disease impacts people's health and lives. I have a longstanding research focus on opioids that I describe below. I earned my M.D. and Ph.D. in Economics from the University of Chicago and my Bachelors in Biology and Economics from the Massachusetts Institute of Technology.

2. As an economist, I specialize in the economics of physician behavior, the economics of health care productivity, prescription opioid misuse, and the economics of medical innovation. I am a faculty research fellow at the National Bureau of Economic Research, the nation's leading nonprofit economic research organization. I have published nearly 150 peer-reviewed articles in leading medical and economics journals, including the *New England Journal of Medicine*, *Journal of the American Medical Association*, *British Medical Journal*, *Journal of Health Economics*, *Journal of Public Economics*, and *Journal of Economic Perspectives*. From 2014 to 2015, I served on the Institute of Medicine Committee on Diagnostic Errors in Health Care, which was tasked with preparing a follow-on report to the previous highly influential IOM

reports, *To Err is Human* and *Crossing the Quality Chasm*, with the current report focusing on the epidemiology, causes, and policy solutions for diagnostic errors in medicine. In 2016 and 2018, I served on the Centers for Medicare and Medicaid Services (CMS) Technical Expert Panel for episode-based resource use measures, which provided advice to CMS on how to design pay-for-performance measures for individual physicians based on their costs of care when treating patients. Since 2018, I have served on the Advisory Committee on Emerging Science, Technology, and Innovation for the National Academy of Medicine (formerly, the Institute of Medicine). In addition to my academic research, I have consulted for the government, the insurance industry, and pharmaceutical firms on issues related to the economics of pharmaceutical innovation.

3. In addition to my clinical work, I have a longstanding research agenda focused on prescription opioids. I have published multiple studies of prescription opioid misuse in leading journals of medicine and health policy including the *New England Journal of Medicine, Journal of the American Medical Association, British Medical Journal, Annals of Internal Medicine,* and *Health Affairs*. I am among the first researchers to document the widespread variation in opioid prescribing that occurs between hospitals and between individual physicians who practice within hospitals; this research demonstrates the important but under-recognized role that health care providers (both hospitals and physicians) play in driving opioid prescribing. I have studied patterns of misuse of opioids and have performed one of the most comprehensive assessments of how opioid misuse patterns should be measured and how misuse relates to long-term adverse outcomes related to opioids. My research on prescription opioid use in Medicare was also the first to document at a national level the degree to which fragmentation in prescribing of opioids by multiple doctors occurs in the elderly American population and the relationship between fragmented prescribing and downstream adverse patient outcomes. I have also studied the impact of government efforts to reduce opioid prescribing by health care providers, e.g. provider "feedback reports" which aim to reduce opioid prescribing by making providers aware of how often they prescribe opioids relative to peers; the impact of state prescription drug monitoring programs on opioid misuse; and the impact of insurer-led efforts to reduce opioid prescribing, e.g., "quantity limits" on certain prescription opioids. I have also examined the role of illegitimate online pharmacies in contributing to the early stages of the current opioid epidemic. Finally, I was a co-author of the Society of Hospital Medicine's

clinical guidelines and recommendations for prescribing opioids for acute non-cancer pain in the inpatient setting.

4. In 2007, I was awarded the Eugene Garfield Award by Research America for my work demonstrating the economic value of medical innovation in HIV/AIDS. In 2013, I received the National Institutes of Health Director's Early Independence Award to fund research on the physician determinants of health care spending, quality, and patient outcomes. In 2015, I was awarded the International Society for Pharmacoeconomics and Outcomes Research New Investigator Award. I have lectured internationally and was named one of the 60 Most Powerful People in Health Care in 2016 and one of the 100 Great Leaders in Health Care in 2018 by *Becker's Hospital Review*. My research and scholarly opinions have been published in the *New York Times*, *Washington Post*, *Wall Street Journal*, *Harvard Business Review*, and other places. My curriculum vitae is attached as Appendix A. A list of my testimony in the last four years is contained in Appendix B.

B. Assignment

5. I have been retained by Rite Aid Headquarters Corporation and its affiliated entities, including Rite Aid Mid-Atlantic, to opine on Plaintiffs' methodologies for identifying allegedly suspicious orders distributed by Rite Aid Mid-Atlantic. I understand that pursuant to the Controlled Substances Act and its implementing regulations, distributors of controlled substances are required to "maint[ain]… effective controls against diversion of … controlled substances … into other than legitimate medical, scientific, or industrial channels."[1] As part of those controls, distributors are required to "design and operate a system to disclose to the registrant suspicious orders" and to report those orders to the DEA, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[2] In addition, I was asked to evaluate Plaintiffs' assessment of alleged harm resulting from Rite Aid Mid-Atlantic's distribution of opioid products. As part of this assignment, I have been asked to consider the opinions of Plaintiffs' experts on these topics,

[1] 21 USC §823(a)(1); and 21 USC §823(d)(1). *See* also 21 CFR §1301.71(a) (requiring that distributors "provide effective controls and procedures to guard against theft and diversion of controlled substances.").

[2] 21 CFR §1301.74(b).

including Craig McCann, Jonathan Gruber, David Cutler, James Rafalski, and Seth Whitelaw, among others.[3]

6. This report and the opinions expressed in it are based on my analysis of the information and materials available to me as of this date as well as my training in economics and medicine. To the extent I rely on my medical training and clinical experience to reach any opinions expressed in this report, I hold those opinions to a reasonable degree of medical certainty. I reserve the right to supplement this report in the event that new information relevant to my opinions is produced in this case.[4] A list of the materials that I have considered for my assignment is included in Appendix C.

7. I am being compensated for my work in this case at the rate of $875 per hour. Part of the work for this report was performed by professional staff at Analysis Group, Inc. under my direction. I also receive compensation based on the professional fees of Analysis Group, Inc. This compensation is not contingent on the nature of my findings or the outcome of this litigation. I understand that Rite Aid Mid-Atlantic and other defendants in the above-referenced litigation may use my expert testimony at trial.

II. SUMMARY OF CONCLUSIONS

8. I have reached the following four primary conclusions.

9. <u>First, Rite Aid Mid-Atlantic maintained substantial controls against diversion of opioids.</u>

10. Plaintiffs claim that distributors, including Rite Aid Mid-Atlantic, failed to maintain effective controls against diversion of opioids. Rite Aid had multiple anti-diversion measures in place during and prior to the years at issue here. These included inventory control measures and

[3] Expert Report of Craig J. McCann, Ph.D., CFA, March 25, 2019 ("McCann Report"); Expert Report of Professor Jonathan Gruber, March 25, 2019 ("Gruber Report"); Expert Report of Professor David Cutler, March 25, 2019 ("Cutler Report"); Expert Report of James E. Rafalski, April 15, 2019 ("Rafalski Report); Expert Report of Dr. Seth B. Whitelaw, April 15, 2019 ("Whitelaw Report"). Appendix D to this report provides a complete list of Plaintiffs' expert reports received as of the date of this report. I understand that Plaintiffs have withdrawn Dr. Ballantyne, Dr. Miller, Dr. Parran, and Dr. Schondelmeyer as proposed experts in this litigation. To the extent I do not address specific opinions offered by these, or other experts, in this report, this should not be interpreted as my endorsement of the opinion.

[4] In particular, I have not had the opportunity to review the deposition transcripts of Dr. McCann and Mr. Rafalski. I reserve the right to review his deposition testimony and provide additional opinions should they be warranted.

order control and monitoring measures at Rite Aid Mid-Atlantic and an asset protection division at Rite Aid Headquarters Corporation. Procedures implemented throughout Rite Aid controlled against diversion by preventing orders of unusual size, frequency, or pattern, among other things.

11. In my opinion as an economist, physician, and health policy researcher, Rite Aid Mid-Atlantic's policies and procedures limited the risk of diversion and demonstrated effectiveness. In particular, Rite Aid Mid-Atlantic: (1) passed every state and federal inspection, suggesting the appropriateness of its anti-diversion measures, (2) never distributed schedule II drugs, a more potent class of opioids, (3) distributed only to Rite Aid pharmacies, which permitted an additional layer of monitoring, (4) accounted for less than one percent of opioids distributed to Cuyahoga and Summit Counties, and (5) had stable or declining opioid shipment volumes during the period at issue, despite the fact that total opioid distribution to Cuyahoga and Summit Counties was increasing over the period.

12. Second, Plaintiffs' methodology for identifying suspicious orders is flawed and unreliable.

13. In my opinion as an economist, physician, and health policy researcher, identifying opioid transactions as being suspicious is a non-trivial empirical exercise and one that, at a minimum, must explicitly demonstrate why the allegedly suspicious transactions reflect diversion. For example, were specific Rite Aid Mid-Atlantic flagged transactions linked to evidence that Rite Aid Mid-Atlantic did not have sufficient controls against opioid diversion? Were flagged transactions specifically linked to diversion? Dr. McCann's approach to flagging suspicious opioid transactions does not address these issues and, as a result, his methodologies identify implausibly high rates of purportedly suspicious opioid transactions.

14. Dr. McCann implements five approaches to flag transactions. Although Dr. McCann does not identify the flagged transactions as suspicious orders, James Rafalski, Plaintiffs' expert on statutory and regulatory compliance, refers to Dr. McCann's approaches as suspicious order methodologies. Each of Dr. McCann's five approaches for flagging transactions is unreliable as a method for identifying suspicious orders. Among other flaws, these approaches do not allow for legitimate growth in Rite Aid Mid-Atlantic's distribution volume and do not account for variation in the size and composition of the populations Rite Aid Mid-Atlantic's customers serve. In addition, Dr. McCann provides no support for his methodologies and calculations.

He does not say why he implemented these five methods and he cites to no academic or industry sources to justify his calculations. In my expertise, they are not justified and lack a theoretical grounding.

15. Dr. McCann states the he was instructed to "assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction." He essentially argues that *none* of the opioid prescriptions distributed subsequent to a flagged transaction could reflect legitimate prescriptions for patients who may benefit from opioids. Put differently, if Rite Aid Mid-Atlantic were to have acted on the basis of Dr. McCann's suspicious order methodology, or a similar methodology, a significant number of patients with legitimate pain needs would be potentially unable to fill prescriptions for opioids at a Rite Aid pharmacy located in Cuyahoga or Summit County. A methodology that lacks the ability to accurately separate appropriate opioid use from outright diversion is not a valid methodology.

16. Furthermore, I conduct additional analyses that convincingly and transparently show Dr. McCann's methodologies for flagging transactions are not able to reliably identify suspicious orders. If applied to non-opioid transactions, such as commonly prescribed medications to help lower cholesterol, Dr. McCann's methods flag large numbers of those transactions. This is consistent with his methods flagging transactions inappropriately, simply due to normal variation in distribution patterns rather than distribution patterns suggestive of opioid diversion. When applied to shipments from a distributor to a doctor who has been found to have illegally distributed opioids, Dr. McCann's transaction analysis fails to flag all of the transactions. The fact that Dr. McCann's methodologies flag the Rite Aid Mid-Atlantic transactions at *higher* rates than those for the shipments to a known fraudulent prescriber and a known illicit pharmacy demonstrates that Dr. McCann's method is effectively useless for purposes of evaluating harm caused by distributors' actions.

17. <u>Third, Plaintiffs provide no assessment of harm resulting from Rite Aid Mid-Atlantic's role in distributing hydrocodone combination products.</u>

18. I have reviewed the reports filed by the 19 experts proposed by Plaintiffs in this matter. Plaintiffs' experts provide no analysis demonstrating that Rite Aid Mid-Atlantic failed to

maintain effective controls against diversion and I have seen no analysis showing any specific harm resulting from Rite Aid Mid-Atlantic's distribution of hydrocodone combination products (HCPs) to Rite Aid pharmacies in Cuyahoga and Summit Counties. In fact, only 8 of the 19 experts specifically reference any Rite Aid entity and only Dr. McCann evaluates Rite Aid Mid-Atlantic.

19. Fourth, Plaintiffs' characterization of Rite Aid Mid-Atlantic's role in the distribution of opioid products fails to consider the role of physicians.

20. A number of Plaintiffs' experts comment on the role of physicians and prescribers in regards to the distribution of opioid products. These experts, however, fail to connect how medical professional prescribing relates to Rite Aid Mid-Atlantic's distribution of opioids. In my opinion, much of the opioid epidemic that we are witnessing today is a function of inappropriate, *routine* prescribing of opioids to many patients by many physicians, which is a very different issue than diversion. Rite Aid Mid-Atlantic, as a distributor, was supplying opioids to Rite Aid pharmacies that were filling opioid prescriptions by the many physicians whose routine opioid prescribing may have unintentionally led to long-term opioid dependence. Any characterization by Plaintiffs that Rite Aid Mid-Atlantic was encouraging opioid product sales and thereby increasing demand for the products while intentionally ignoring patient safety is incorrect and at a minimum must rigorously consider the role of providers in driving this opioid use. The Plaintiffs' arguments trivialize the critical role that physicians play in driving pharmaceutical demand, changes in medical knowledge over this time period, and changes in regulatory efforts to monitor opioid use.

III. BACKGROUND ON OPIOID DEVELOPMENT AND USE IN MEDICAL TREATMENTS

21. In this section I provide an introduction to the products at issue in this litigation by briefly describing the development and use of opioids as medical treatments in the past few decades. I then describe a commonly used framework for assessing healthcare quality that can also be used as a framework to evaluate prescription opioid distribution systems, particularly as they relate to controlling diversion.

A. Summary of opioid products used by medical professionals

22. Since the introduction of OxyContin in 1995, the medical community has become more aware of pain management. Opioid products are one part of the pain management tools utilized by physicians. This remains true to this day. The use of opioid products for medical treatment can be beneficial to patients, but these products also can present significant, legitimate risks. Indeed, opioid use is warranted in many clinical settings, for example, in patients with orthopedic injuries, those undergoing surgery, and those receiving palliative care.[5] Failure to manage pain in these settings may adversely affect patient quality of life, delay hospital discharge, and disrupt postoperative rehabilitation for surgical patients and lead to chronic postsurgical pain.[6] However, opioid prescriptions are also associated with both short- and long-term risks including physical dependence.[7] The Centers for Disease Control and Prevention (CDC) has classified prescription opioid abuse as an epidemic and issued specific recommendations for prescribing.[8] In 2017, the epidemic was declared a national public health emergency.[9]

23. With recent declines in opioid prescribing due to increased provider awareness of the potential risks of opioids and widespread policy efforts to reduce inappropriate prescribing, some have raised concerns that the much-needed reduction in inappropriate prescribed use of opioids has been met with reductions in appropriate use as well, leaving some patients with pain in need, and highlighting the tension of appropriately prescribing medications with such large risk-benefit tradeoffs. As I describe later in this report, one of the critical flaws of Plaintiffs' expert Dr. McCann is that he fails to recognize that a *complete* cessation of opioid dispensation by a distributor to a pharmacy, as he insinuates should have occurred when certain suspicious ordering thresholds were met in a given pharmacy, could have significant adverse clinical implications.

---

5 Jena, Anupam B., et al., "Hospital Prescribing of Opioids to Medicare Beneficiaries," *JAMA Internal Medicine*, Vol. 176, No. 7, July 2016, pp. 990-997 (hereafter, "Jena, et al. (2016)") at p. 991.

6 *Id*.

7 *Id*.

8 CDC, "CDC's Response to the Opioid Overdose Epidemic," available at: https://www.cdc.gov/opioids/strategy.html, accessed May 9, 2019.

9 The White House, "Ending America's Opioid Crisis," available at https://www.whitehouse.gov/opioids/, accessed May 9, 2019.

24. Given the potential for abuse and likelihood of dependence of different opioid products, these drugs are covered under the Controlled Substances Act (CSA). The CSA was enacted in 1971 to "improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances."[10] Under the CSA, controlled substances are divided into five schedules based on whether the substance has an accepted medical use in the United States, its abuse potential, and the likelihood of dependence.[11] Schedule I controlled substances have no accepted medical use in the United States and a high potential for abuse (e.g., heroin, ecstasy), while schedule V substances have the lowest potential for abuse.[12] Most licit opioids are schedule II substances (e.g., oxycodone, morphine, opium), while some are schedule III or even schedule V.[13] Schedule III drugs have a lower potential for abuse than schedule II drugs.[14]

25. **Exhibit 1** summarizes the schedule, common brand names, and uses for the fourteen opioids in the ARCOS data produced by the DEA.[15]

---

[10] Gabay, Michael, "The Federal Controlled Substances Act: Schedules and Pharmacy Registration," *Hospital Pharmacy*, 2013, Vol. 48, No, 6, 2013, pp. 473-374, at p. 473.

[11] United States Department of Justice, Drug Enforcement Administration, Diversion Control Diversion, "Controlled Substance Schedules," December 2018, available at https://www.deadiversion.usdoj.gov/schedules/, accessed April 2, 2019.

[12] *Id*.

[13] *Id*.

[14] *Id*.

[15] ARCOS data files ("ARCOS Data Files"):
"confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419.txt";
"confidential_arcos_200060101-20141231_all_states_20180625.txt";
"confidential_arcos_20060101-20141231_all_exclude_6states_20180525.txt";
"confidential_arcos_20060101-20141231_all_states_20180621.txt"; and
"confidential_arcos_20060101-20141231_9220L_9250B_all_states_20180625.txt."

Exhibit 1
Current Schedule of Opioids in ARCOS Transaction Data Produced by the DEA

Drug	Brand Names	Schedule	MME Conversion Factor
Buprenorphine	Buprenex, Suboxone, Subutex	III	Film/tablet: 30/mg Patch: 12.6/mcg/hr Film: 0.03/mcg
Codeine	III: Tylenol with Codeine V: Robitussin AC	II, III, or V depending on dosage	0.15/mg
Dihydrocodeine	**Combination products:** Drocode, Paracodeine, Parzone, Trezix	II	0.25/mg
Fentanyl	Actiq, Fentora, Duragesic	II	Buccal/tablets/lozenge/troche: 0.13/mcg Film or oral spray: 0.18/mcg Nasal spray: 0.16/mcg Patch: 7.2/mcg
Hydrocodone	**Alone:** Hysingla **Combination products:** Vicodin, Lortab, Lorcet-HD, Hycodan	II	1/mg
Hydromorphone	Dilaudid	II	4/mcg
Levorphanol	Levo-Dromoran	II	11/mg
Meperidine (Pethidine)	Demerol	II	0.1/mg
Methadone	Dolophine	II	>0,<=20 mg: 4/mg >20, <=40: 8/mg >40, <=60: 10/mg >60: 12/mg
Morphine	Avinza, Morphabond, Oramorph SR, Roxanol-T	II	1/mg
Opium - Powdered		II	1/mg
Oxycodone	**Alone:** OxyContin **Combination products:** Percocet, Percodan	II	1.5/mg
Oxymorphone	Opana	II	3/mg
Tapendatol	Nucynta	II	0.4/mg

Notes:
[1] The DEA rescheduled hydrocodone combination products from schedule III to schedule II on October 6, 2014.
[2] Levo-Dromoran was discontinued in July 2015.

Sources:
[A] United States Department of Justice, Drug Enforcement Administration, "Drug Scheduling," available at https://www.dea.gov/drug-scheduling, accessed April 2, 2019.
[B] United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, "Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II," 79 FR 49661, August 22, 2014, available at https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm, accessed April 4, 2019.
[C] United States Department of Health & Human Services, National Institutes of Health, National Library of Medicine, MedlinePlus.
[D] United States Department of Justice, Drug Enforcement Administration, Drug & Chemical Evaluation Section.

26. Rite Aid Mid-Atlantic never distributed schedule II drugs. While pure hydrocodone and HCPs are both currently schedule II substances, the DEA rescheduled HCPs from schedule III to schedule II on October 6, 2014.[16] At this time, when HCPs were moved to the higher risk schedule II, Rite Aid Mid-Atlantic discontinued distribution of HCPs.[17] As seen in this exhibit, buprenorphine, typically used to treat opioid dependence, is a schedule III substance, while codeine forms are schedule II, III or V depending on the quantity of the narcotic in the drug. The rest of the opioids are schedule II substances (dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, methadone, meperidine, morphine, opium, oxycodone, oxymorphone, tapendatol). With the exception of buprenorphine and methadone, which are used to treat opioid addiction, the other twelve opioids in **Exhibit 1** are used to treat pain, with slightly different uses depending on the substance.

27. Opioids differ in their potency. To assist physicians with prescribing opioids and to provide a standard way of measuring quantities across opioids, an "opioid conversion factor" has been developed, and has become a standard means of measuring quantities of opioids.[18] This factor is designed to convert the quantity of each drug into units that are equivalent to milligrams of morphine, or morphine milligram equivalents ("MME"). The MME conversion factor is shown in **Exhibit 1**. As can be seen in the exhibit, the conversion factor varies by strength for some opioids. Drugs with higher conversion factors are more potent. For example, the MME conversion factor is equal to 1 for hydrocodone and 1.5 for oxycodone.[19] This means that 10 mg of hydrocodone is equivalent to 10 mg of morphine, but 10 mg of oxycodone is equivalent to 15 mg of morphine. In other words, oxycodone is 50 percent more potent than hydrocodone.

28. An alternative measure that does not account for potency is "dosage units." For pills, one pill is one dosage unit. For example, a 10 mg hydrocodone pill is one dosage unit, as is a 10 mg oxycodone pill, regardless of the fact that oxycodone is more potent than hydrocodone.

---

16 United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, "Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II," 79 FR 49661, August 22, 2014, available at https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm, accessed April 4, 2019 (hereafter, "DEA, Rescheduling of Hydrocodone Combination Products (August 2014)").

17 ARCOS Data Files.

18 United States Department of Health and Human Services, Centers for Disease Control and Prevention, "Calculating Total Daily Dose of Opioids for Safer Dosage."

19 *Id*.

Similarly, a 2.5 mg, 5 mg, and 10 mg oxycodone pill are all equal to one dosage unit, even though a 10 mg pill has four times as much oxycodone than a 2.5 mg pill. And although an 80 mg oxycodone tablet has the same dosage unit as a 15 mg codeine with acetaminophen tablet, the diversion of the oxycodone tablet is likely to be far more dangerous as it is significantly more potent. For these reasons, assessing the potential harm from opioid diversion using dosage units will be misleading, as it does not account for the potency of the drug. Using MMEs helps correct for this issue.

B. Framework for assessing prescription opioid use and distribution systems

29. Given both the potential benefits and risks associated with opioid products, an important health policy goal is to find the right balance between "ensur[ing] an adequate supply of controlled substances for legitimate needs while preventing diversion into the illicit market."[20] I distinguish between two forms of opioid misuse, illicit use and clinically inappropriate (but still licit) use, because suspicious order monitoring relates to illicit use (i.e., diversion) rather than the routine overprescribing of opioids that my and other research has shown to have large adverse effects on patients. Plaintiffs' expert Dr. McCann, in his evaluation of suspicious ordering, seems not to recognize this important distinction.

30. Critical to the risk-benefit balance of opioid prescribing and upstream distribution are processes and systems used to prevent the diversion of opioid products for non-medical purposes. In my own research, I have evaluated how the processes used to deliver prescription medications including opioid products can contribute to misuse.[21] In other research, I have examined how better surveillance of illegitimate pharmacies and online drug distributors may lead to substantial reductions in prescription drug abuse.[22] I have also written on the role of various policies and interventions used to address opioid abuse (e.g., prescription drug monitoring programs, 'feedback reports' to doctors on their own opioid prescribing habit, and

---

20 CAH_MDL_PRIORPROD_DEA12_00011059.

21 Jena, Anupam B., et al., "Prescription Medication Abuse and Illegitimate Internet-Based Pharmacies," *Annals of Internal Medicine*, Vol. 155, No. 12, December 2011, pp. 848-850 (hereafter, "Jena, et al. (2011)").

22 Jena, Anupam B. and Dana Goldman, "Growing Internet Use May Help Explain the Rise in Prescription Drug Abuse in the United States," *Health Affairs*, Vol. 30, No. 6, June 2011, pp. 1192-1199 (hereafter, "Jena and Goldman (2011)").

insurer-driven prescription limits), and the available evidence demonstrating the effectiveness of these measures.[23]

31. Much of my research on prescription opioid abuse relates to assessing the systems in which opioid products are prescribed by medical professionals and are then distributed to patients. In healthcare settings, a frequently used framework of evaluating health care systems is through the triad of "structure," "process," and "outcome."[24] Within this framework, "structure" embodies the settings, qualifications of providers, and administrative systems through which care takes place, "process" includes the components of care delivered, and "outcomes" refer to clinically relevant endpoints such as morbidity and mortality.[25] With prescription opioid products, the method of distribution of the drugs can be viewed as part of the "structure" of the system. In that sense, assessing the quality of prescription opioid use and distribution requires evaluation of the structure of the opioid distribution chain, including the systems in place to prevent the diversion of opioid products for non-medical uses.

32. As a healthcare professional, economist, and health policy researcher, it is through this lens that I have evaluated different approaches to prevent inappropriate use of opioid products. The conceptual framework described above can be applied to assessing the structure and controls put in place by Rite Aid Mid-Atlantic to maintain effective controls against diversion while balancing the equally important need to ensure an adequate supply of controlled substances for legitimate medical needs, as well as the Plaintiffs' methods for identifying allegedly suspicious orders. I do this in the following sections.

---

[23] Barnett, Michael L., et al., "Coupling Policymaking with Evaluation — The Case of the Opioid Crisis," *The New England Journal of Medicine*, Vol. 377, No. 24, 2017, pp. 2306-2309; Barnett, Michael L., et al., "A Health Plan's Formulary Led To Reduced Use of Extended-Release Opioids but Did Not Lower Overall Opioid Use," *Health Affairs*, Vol. 37, No. 9, 2018, pp. 1509-1516; Jena, et al. (2011); and Haffajee, Rebecca L., et al., "Mandatory Use of Prescription Drug Monitoring Programs," *JAMA*, Vol. 313, No. 9, March 2015, at pp. 891-892 (hereafter, "Haffajee, et al. (2015)").

[24] *See* Avedis Donabedian's seminal work on evaluating the quality of medical care. "Evaluating the Quality of Medical Care," *The Milbank Memorial Fund Quarterly*, Vol. 44, No. 3, Pt. 2, 1966, pp. 166-203.

[25] Ayanian, John Z. and Howard Markel, "Donabedian's Lasting Framework for Health Care Quality," *The New England Journal of Medicine*, Vol. 375, No. 3, July 2016, pp. 205-207.

IV. RITE AID MID-ATLANTIC MAINTAINED SUBSTANTIAL CONTROLS AGAINST DIVERSION OF OPIOIDS

A. Rite Aid Mid-Atlantic maintained controls against diversion

33. Plaintiffs claim that distributors, including Rite Aid Mid-Atlantic, failed to maintain effective controls against diversion of opioids. Diversion of opioids occurs when "legally obtained opioids are transferred from a licit to an illicit channel of distribution or use."[26] In fact, Rite Aid had multiple measures in place to prevent diversion throughout the years at issue, and earlier, and passed numerous inspections conducted by state and federal agencies.[27]

34. One component of maintaining effective controls against diversion is to employ a suspicious order monitoring system (SOM), which Rite Aid Mid-Atlantic did. As an initial matter, it is important to note that the DEA never had explicit requirements for exactly how a suspicious order monitoring system should work and it did not establish a common system across all distributors.[28] As Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA, testified, there is no one-size-fits-all proposition for SOM systems.[29] Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, noted in his deposition that it was not the DEA's policy to tell distributors whether an order was suspicious or not, as that was a decision that "only" the distributor could make because they

---

[26] Jena, Anupam B., et al., "Opioid Prescribing By Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims," *BMJ*, 348:g1393, 2014, p. 2.

[27] Rite_Aid_OMDL_0014804-74, at 05 and 28; Rite_Aid_OMDL_0047171-72; Rite_Aid_OMDL_0032629-33; Rite_Aid_OMDL_0016988-89; Rite_Aid_OMDL_0012516-17; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032621; Rite_Aid_OMDL_0012547; Rite_Aid_OMDL_0032618-19; Rite_Aid_OMDL_0032614-17; Rite_Aid_OMDL_0036784-87; and Rite_Aid_OMDL_0032612-13.

[28] This notion was confirmed by one of Plaintiffs' suspicious order monitoring experts in in his expert report. Rafalski Report, pp. 12-13 ("Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ('SOMS'), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done."). *See also*, Deposition of Kyle Wright, Unit Chief of the Targeting and Analysis Section at the DEA, February 28, 2019 (hereafter, "Wright Deposition"), pp. 128-129 ("Q. And it was understood, with the move toward the Suspicious Order Monitoring Program, that not every company would necessarily have the exact same type of program; fair? […] A. Yes, ma'am. Q. And, in fact, DEA wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might service, correct? […] A. Yes, ma'am.").

[29] Deposition of Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA , April 17-18, 2019 (hereafter, "Prevoznik Deposition"), p. 446 ("Q. Is it fair to say that a SOMs systems is not a one-size-all proposition, one-size-fits-all proposition? A. Correct.").

"know their customer."[30] Ultimately, it is the DEA's expectation that each distributor will review its own business model and design a SOM system that fits its specific method of distribution.[31]

35. Rite Aid had multiple anti-diversion measures in place during and prior to the years at issue here. These included inventory control measures, order control and monitoring measures, and an asset protection division.

1. Rite Aid Mid-Atlantic's inventory control measures

36. Rite Aid Mid-Atlantic's inventory control measures included the following:

- [redacted][32]
- Physical inventories of each "pick" location were conducted twice a day (one for the day shift and one for the night shift).[35] Additionally, complete inventories of the

---

30 Deposition of Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, April 26, 2019 (hereafter, "Rannazzisi Deposition"), pp. 42-43 ("Q. And it was DEA's policy not to tell registrants that an order is or is not suspicious, correct? A. Well, that's a business decision that only the -- the distributor could make. They're the only ones who know their customer. And they know what their customers are doing. And they know the -- the population around the customer's business. They know what is in the area that could warrant an increase or not.").

31 Prevoznik Deposition, p. 447 ("Q. And DEA expects that each registrant will review its own business model and design a SOM system that fits its specific method of distribution? […] A. That's correct as -- as per the regulations.").

32 Deposition of Keith Frost, Department Manager for Pharmacy, Cigarettes, and Centralized Product Departments at Rite Aid Perryman Distribution Center, January 15, 2019 (hereafter, "Frost Deposition"), pp. 18, 27; Deposition of Larry Ringgold, DEA Coordinator for Security of Rite Aid, January 24, 2019 (hereafter, "Ringgold Deposition"), p. 115.

33 Ringgold Deposition, pp. 93, 89-90.

34 [redacted]

35 Frost Deposition, pp. 18-19 ("Q. When you say they pick, what do you mean they pick? A. Our associates get the items and put them in packages or totes to send to our customer stores. Q. So they're actually picking the items out of some group of inventory to be delivered to the stores? A. Yes, out of forward pick. Q. What's a forward pick? A. A forward pick is a location where the product is loose in boxes or sometimes it could be cases. It's an area where, when the orders download, a light lights up. It's called a pick-to-light system. And a number appears. And that's what the store wants of that particular item in that particular location. And the

controlled drug cage were also conducted weekly.[36] In the event that a pharmacy reported a shortage in a shipment of controlled drugs, Rite Aid Mid-Atlantic security personnel conducted a thorough investigation, [redacted][37]

associate goes to that location, look at the number, and puts the item into the tote or box, and then extinguishes the light, and moves onto the next location for the next item that the store wants."); Deposition of Marian Wood, Former DEA Coordinator at Rite Aid Perryman Distribution Center, January 24, 2019 (hereafter, "Wood Deposition"), pp. 175-176 ("Q. Did you prepare this document, the attachment, the daily inventory forward pick locations chart? A. This is what we used to do our inventory every day. And since it had every SKU, it looks to me like she wanted to see what the limits were for each item. Q. Okay. You said you used it to do your inventory each day. Can you explain how you used this doing your inventory? A. Well, the format is for that. These numbers on the side, this column, would be blank. And then these forms were printed out twice a day, day shift and night shift. And we would do a physical inventory of each pick location. Q. Sorry, when you say 'this column would be blank,' you were motioning to the pick limit column? A. I'm sorry, yes. The pick limit column would be the physical inventory column. Q. So you would print this entire spread-sheet every day and use it in your inventory? A. The -- twice a day. I'm assuming this is our entire -- it's about ten pages, I thought. We would -- a form just like this, that would have every single forward pick location on it, day shift would count every location after every shift, and night shift would do the same. Q. When you say 'count each location,' what do you mean by that? A. Count what -- how many -- the physical inventory in that location. Q. So you would go to the physical location of that particular item and see how many were actually in that location, like, meaning on the shelf or in the box or whatever they were held in; is that right? A. Yes."); Frost Deposition, pp. 77-78 ("Q. Are you aware whether Rite Aid as a registrant was required to provide effective controls against diversion? A. Yes. We always had effective controls against diversion. Q. What's your understanding of what diversion is? A. Diversion is any theft, misappropriation, misuse of any pharmacy items, which includes control drugs. Not in -- we had procedures, a lot of procedures in place to make sure that didn't happen. We had SOPs where each associate taking out the trash had to have a lead or a manager inspect for any loose bottles that might have fallen into the trash or got caught up in the -- in the plastic before throwing it away on the conveyor line. Any instances of bottles on -- on the floor, we reported that to the leads and managers […] both shifts, did a forward pick inventory for everything. And we weren't really -- we're not required to do it. There's nothing in the federal regulations for that. They don't require biennial inventory or a annual inventory. We did it daily, the forward picks.").

36 Ringgold Deposition, p. 55.

37 [redacted]

- Investigations were required to be conducted and closed within 48 hours, and security personnel closely tracked and logged details of the investigations.[38]

2. Rite Aid Mid-Atlantic's order control and monitoring measures

37. From the late 1990s,[39] including during the period 2006 through 2014 when it ceased distribution of any controlled drugs, Rite Aid Mid-Atlantic's order control and monitoring measures included three key components that prevented shipment of orders of unusual size, frequency, or pattern:

i. *Shipment Threshold* – Rite Aid Mid-Atlantic employed an order shipment threshold system to control orders. Each order of a controlled drug from a Rite Aid pharmacy to be fulfilled by Rite Aid Mid-Atlantic was subject to a threshold limit unless a pre-existing exception was in place. For virtually all Rite Aid pharmacies supplied by Rite Aid Mid-Atlantic, this limit was 5,000 dosage units per NDC per order.[40] The order threshold system helped ensure that orders were not unusually large because quantities were not shipped above the shipment threshold.

ii. *Auto Replenishment System (ARS)* – Rite Aid Headquarters Corporation used an ARS to calculate and limit orders from pharmacies through the use of algorithms.[41] The ARS created a suggested order for each pharmacy based on the prior [redacted] dispensing

[redacted]

38 *Id.*, pp. 48 - 50, 51-52 ("A. Some -- he asked me to keep track and keep him updated weekly on shortage cases […] Q. Can you explain to me what this particular page represents? A. Weekly investigation tracking sheet, meaning for that week, store numbers, as it explains, dates received, the product, shortage claim, pending date, open or close […] we had a time limit on trying to close cases. Q. Those would be shortage claim cases? A. Yes. Q. What was the time limit to close those? A. I believe we had 48 hours.").

39 Deposition of Janet Getzey Hart, Director of Government Affairs at Rite Aid, January 30, 2019, p. 83.

40 "Rite Aid of Maryland, Inc.'s Second Supplemental Objections and Answers to Plaintiffs' First Set of Interrogatories," January 25, 2019 (hereafter, "Rite Aid's Second Supplemental Objections (2019)"), p. 13. Between 2006 and 2014, only one store serviced by Rite Aid Mid-Atlantic in Cuyahoga or Summit Counties was permitted an exception to the 5,000 unit threshold rule. Store 3151 was granted an exception to Rite Aid of Maryland's threshold between 2011 and 2013 with regard to a single hydrocodone combination product and had a higher dosage unit order threshold for that particular product. Even with the exception, the store ordered more than 5,000 units only seven times between 2011 and 2013. *See* Rite_Aid_OMDL_0012504-05; Rite_Aid_OMDL_0023818; Rite_Aid_OMDL_004657-71; and Rite_Aid_OMDL_0014294.

41 Rite Aid's Second Supplemental Objections (2019), p. 15.

history and inventory.[42] Pharmacists could override the suggested order, but only within specific limits.[43] The order could not be more than [redacted].[44] The ARS thus further ensured that orders were not of unusual size and did not deviate substantially from the normal pattern of ordering.

iii. *Scheduled Shipments* – The frequency with which pharmacies received shipments was pre-determined and set by Rite Aid Headquarters Corporation and could not be altered by pharmacy personnel. Based on a pharmacy's size and storage capacity, pharmacies received orders once per week, twice per week, or every other week. The majority of pharmacies received orders once per week.[45] This regular shipment schedule prevented concerns about unusual order frequency.

3. Rite Aid's Asset Protection department

38. In addition, Rite Aid Headquarters Corporation has an "Asset Protection" department. Employees in that department analyze reports and data related to pharmacy orders and did so during the time period that Rite Aid Mid-Atlantic distributed opioids (i.e., before November 2014).[46] Employees reviewed and analyzed Above Average Controlled Drug Purchases reports that compared the amount of controlled substances purchased and dispensed at a pharmacy level.[47] The Asset Protection department also reviewed a set of "key performance indicators" ("KPIs") relating to pharmacy orders for potential anomalies.[48] If the department detected anomalies in the KPIs, it would initiate an investigation.[49] These investigations could involve a number of additional actions (e.g., installation of additional surveillance cameras) to capture evidence of diversion, with the ultimate possible outcome being reports to law

---

42 *Id*.
43 *Id*.
44 *Id*., pp. 15-16.
45 Deposition of Janet Getzey Hart, Director of Government Affairs at Rite Aid, January 31, 2019, pp. 79-80 ("Q. And so orders are placed by Rite Aid stores with a regular frequency. Correct? A. Orders are placed once a week, once every other week in a limited number of stores, and twice a week in a very limited number of stores. Q. So let me break that down. So most -- what most -- what's the ordering pattern for most stores? A. Most stores, Rite Aid places an order once a week.").
46 Rite_Aid_OMDL_0032602.
47 Rite Aid's Second Supplemental Objections (2019), p. 16.
48 *Id*., p. 16.
49 *Id*., p. 16-17.

enforcement and Boards of Pharmacy regarding internal theft and arrest warrants being issued.[50]

B. Rite Aid Mid-Atlantic's policies and procedures limited the risk of diversion and demonstrated effectiveness

39. The following five facts documented in this section are consistent with the effectiveness of Rite Aid Mid-Atlantic's previously described anti-diversion measures, its overall policy on the distribution of schedule II drugs, and its distribution structure: Rite Aid Mid-Atlantic (1) passed every state and federal inspection, suggesting the appropriateness of its anti-diversion measures, (2) never distributed schedule II drugs, a more potent class of opioids, (3) distributed only to Rite Aid pharmacies, which permitted an additional layer of monitoring, (4) accounted for less than one percent of opioids distributed to Cuyahoga and Summit Counties, and (5) had stable opioid shipment volumes during the period at issue, despite the fact that total opioid distribution to Cuyahoga and Summit Counties was increasing over the period.

1. Rite Aid Mid-Atlantic passed every inspection

40. From 2005-2014, the DEA audited Rite Aid Mid-Atlantic's controls against diversion, including its suspicious order monitoring system, in four unannounced audits and found no deficiencies.[51] Similarly, the State of Maryland performed several inspections of the facility during the relevant time period, including anti-diversion methods, and also found no deficiencies.[52] For example, the State of Maryland's Board of Pharmacy examined Rite Aid Mid-Atlantic's inventory control measures in 2010 and again in 2012 and found that it had a "security system that provides protection against theft and diversion" and an "inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting."[53] In addition, in both inspections, the State of Maryland

---

50 Rite_Aid_OMDL_0037816-51 ("Anatomy of a Pharmacy Case" presentation by Andy Palmer), at 34-48.

51 Rite_Aid_OMDL_004717-72; Rite_Aid_OMDL_0012516-17; Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032618-19; and Rite_Aid_OMDL_0032602. The only recommendations were to "repair wire mesh on cage" and to "add a camera directly over the area where we receive and break down the cage receipts." *See* Rite_Aid_OMDL_0032620.

52 The only recommendation from the State of Maryland was to identify a carrier tracking number when reporting a vendor shortage. Rite_Aid_OMDL_0032629-33; Rite_Aid_OMDL_0016988-89; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032614-17; and Rite_Aid_OMDL_0036784-87.

53 Rite_Aid_OMDL_0032622-28 at 25; and Rite_Aid_OMDL_0032614-17 at 16.

found that Rite Aid Mid-Atlantic "maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred."[54] Similarly, the State of Maryland's Division of Drug Control found that Rite Aid Mid-Atlantic "provide[d] effective controls and procedures to guard against theft and diversion" in 2009 and 2012.[55] **Exhibit 2** summarizes the findings of the inspections from the DEA and the State of Maryland.

[54] Rite_Aid_OMDL_0032622-28 at 26; and Rite_Aid_OMDL_0032614-17 at 16.
[55] Rite_Aid_OMDL_0032629-33 at 31; and Rite_Aid_OMDL_0036784-87 at 85.

Exhibit 2
Summary of Rite Aid Mid-Atlantic Inspections
2005-2014

Inspection Date	Inspector	Actions Required/Recommended	Relevant Findings
September 21, 2005	DEA	None	"…no words of advice for the Staff for improvement. It was a flawless audit."
February 4, 2009	Maryland Division of Drug Control	"Please identify carrier tracking number [when reporting a vendor shortage]."	
September 30, 2009	DEA	"…add a camera directly over the area where we receive and break down the cage receipts."	"Everything we saw meets the requirement of what we came to see. I'm happy, very happy."
August 26, 2010	Maryland Board of Pharmacy	None	"Facility ships only to its Rite Aid stores."
July 10, 2012	DEA	"Asked URS to repair wire mesh on cage."	"Both DEA inspectors are very impressed and pleased to see that Rite Aid demonstrates its due diligence by having an excellent excessive order monitoring system."
August 16, 2012	Maryland Board of Pharmacy	None	"Reviewed training documentation, temp logs, invoices, and written policies/procedures."
August 21, 2012	Maryland Division of Drug Control	None	"This facility has a good system for receipt and accountability of CDS [controlled dangerous substances]."
November 17, 2014	DEA	None	[No longer distributing HCPs]

Sources:
[A] Rite_Aid_OMDL_0047171-72.
[B] Rite_Aid_OMDL_0032629-33; and Rite_Aid_OMDL_0016988-89.
[C] Rite_Aid_OMDL_0012516-17.
[D] Rite_Aid_OMDL_0032622-28.
[E] Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032621; Rite_Aid_OMDL_0012547; and Rite_Aid_OMDL_0032618-19.
[F] Rite_Aid_OMDL_0032614-17.
[G] Rite_Aid_OMDL_0036784-87.
[H] Rite_Aid_OMDL_0032602; and Rite_Aid_OMDL_0032612-13.

41. On July 10 and 11 of 2012, two inspectors from the DEA conducted an unannounced audit of Rite Aid Mid-Atlantic.[56] According to Rite Aid Mid-Atlantic's notes of the audit, both of the DEA inspectors were "very impressed and pleased to see that Rite Aid demonstrate[d] its due diligence by having an *excellent* excessive order monitoring program."[57] According to testimony from DEA employees, registrants can rely on guidance from DEA field agents.[58] In the case of Rite Aid Mid-Atlantic, that means accepting the positive feedback from the unannounced DEA audits and not implementing any additional mechanisms to its suspicious order monitoring system. The DEA inspectors also "mentioned that the DEA is taking a harder look at all distributors to ensure that order monitoring processes are in place and effective."[59] Even with the additional scrutiny, the DEA inspectors were pleased with Rite Aid Mid-Atlantic's system and found no deficiencies.

2. Rite Aid Mid-Atlantic did not distribute schedule II opioids

42. Rite Aid Mid-Atlantic never distributed schedule II drugs. From 2006-2014, the only opioids Rite Aid Mid-Atlantic distributed were HCPs.[60] HCPs were schedule III drugs until they were moved to schedule II in October 2014.[61] Rite Aid Mid-Atlantic stopped distributing HCPs when the DEA rescheduled HCPs to schedule II after concluding that HCPs had a higher potential for abuse than previously believed.[62] I understand that Rite Aid Mid-Atlantic stopped distributing all narcotics in November 2014.[63]

---

56 Rite_Aid_OMDL_0032618-19.

57 *Id*.

58 Prevoznik Deposition, p. 461 ("Q. DEA headquarters expects a registrant to listen to the information it receives from DEA field office personnel, true? […] A. Yeah. It depends what they are asking, sure. Q. Okay. And the registrants who are visited by DEA field office personnel can rely on the information that they receive from DEA field division personnel regarding SOMs systems, true? […] A. Yeah, they get guidance."); and Wright Deposition pp. 231-232 ("Q. And based on your experience, you think it would be fair for a registrant to rely on guidance that the registrant received from DEA agents out in the field? […] A. If you make the phone call, you expect to receive a -- an answer. And if you're making that phone call, I think you would rely on the information an then put it together with ever -- other factors that are known to you to make that decision. Q. Okay. And that's the registrant receiving information from DEA, relying on that, and then acting? A. Yes, sir.").

59 Rite_Aid_OMDL_0032618-19.

60 Rite Aid Mid-Atlantic also distributed small amounts of buprenorphine, used to treat opioid use disorder, and schedule III codeine, which are beyond the scope of this litigation. ARCOS Data Files and ECF No. 693 at 3 ("Accordingly, the Special Master RULES as follows. Defendants shall produce discovery related to all opioid products that are or ever were classified as Schedule II under the Controlled Substances Act.").

61 DEA, Rescheduling of Hydrocodone Combination Products (August 2014).

62 ARCOS Data Files.

63 Rite_Aid_OMDL_0032602.

43. The fact that Rite Aid Mid-Atlantic did not distribute schedule II opioids is relevant, since the schedule III drugs Rite Aid Mid-Atlantic distributed had been considered to have a lower risk of abuse than the schedule II drugs Rite Aid Mid-Atlantic chose not to distribute. For example, a study that surveyed the literature on the comparative abuse potential of hydrocodone and oxycodone found that oxycodone demonstrated higher abuse liability than hydrocodone.[64] Other studies have also found that oxycodone is more commonly abused than hydrocodone. For example, one study found that among opioid-dependent subjects entering a drug treatment program, oxycodone was the drug of choice for significantly more users (44.7 percent) than hydrocodone (29.4 percent).[65] Another study found that among individuals entering treatment for opioid use disorder, more individuals initiated regular opioid use with oxycodone rather than hydrocodone every year from 2006 to 2015.[66]

44. As evidence of the higher potential for abuse, schedule II substances have more stringent prescribing guidelines than schedule III to V substances. While schedule III substance prescriptions can be communicated orally, in writing, or by fax to the pharmacist, schedule II substances require a written prescription signed by the practitioner.[67] In addition, prescriptions for schedule III substances can be refilled up to five times within six months after the date of issue, while the refilling of a prescription for schedule II substances is prohibited.[68]

3. Rite Aid Mid-Atlantic distributed to only Rite Aid pharmacies

45. Rite Aid Mid-Atlantic only distributed to Rite Aid pharmacies, not to clinics, individual practitioners, or non-Rite Aid pharmacies.[69] As a result, Rite Aid Mid-Atlantic distributed to

---

64 Wightman, R. et al., "Likeability and Abuse Liability of Commonly Prescribed Opioids," *Journal of Medical Toxicology*, Volume 8, 2012, pp. 335-340.

65 Cicero, Theodore J., et al., "Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States," *International Association for the Study of Pain*, Vol. 154, December 2013, pp. 2639-2648.

66 Cicero, Theodore J., et al., "Increased Use of Heroin as an Initiating Opioid of Abuse," *Addictive Behaviors*, Vol. 74, May 2017, pp. 63-66, at p. 64.

67 DEA, Diversion Control Division, "Practitioner's Manual - Section V," available at https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm, accessed May 9, 2019.

68 *Id*.

69 Deposition of Christopher Belli, Former Senior Director of Regulatory Compliance and Pharmacy Returns for Rite Aid, December 20, 2018, p. 20 ("Q. Do you understand that DC -- Rite-Aid's DC 10 [Mid-Atlantic] was a wholesale distributor? Q. To our internal -- they're inner company sales, so we only ship to our own stores.").

pharmacies that had in place policies and procedures to prevent diversion.[70] This is not necessarily true of all distributors; many distribute to unaffiliated pharmacies with varying degrees of pharmacy-level policies and procedures.

46. Plaintiffs' experts focus on total distributions of opioids, essentially assuming that every opioid pill sold—whether through a "pill mill" or a Rite Aid pharmacy—had an equivalent chance of diversion (and thus inflicted equal harm). As an expert in medicine, economics, and health policy research, it is my opinion that this assumption is false. Some distribution channels—such as rogue internet pharmacies—had a risk of diversion that was significantly higher than diversion of pills sold through chain pharmacies. Any reliable analysis of the harms caused by distribution of opioids must necessarily consider the varying risks of diversion through different channels of distribution.

47. Rite Aid Mid-Atlantic's distribution to only Rite Aid chain pharmacies is particularly important since Rite Aid Mid-Atlantic never distributed to rogue Internet-based pharmacies, a well-known channel for diversion of opioids. My own research has examined the rise in popularity of obtaining controlled prescription medications on the Internet without a valid prescription and the necessity of increased efforts to curb illegitimate Internet-based pharmacies.[71] Furthermore, the DEA focused its efforts on rogue Internet pharmacies and rogue pain clinics, to which Rite Aid Mid-Atlantic never distributed.[72] A presentation by the DEA explicitly states that chain pharmacies, such as those to which Rite Aid Mid-Atlantic distributes, are not rogue pharmacies.[73]

48. Rite Aid Mid-Atlantic also never distributed to opioid "pill mills." Plaintiffs' expert Dr. Gruber created a database of such prosecutions.[74] Of the 165 total prosecutions, only 23

---

70 *See*, e.g., Rite_Aid_OMDL_0044309-17 ("Procedures for Validation and Dispensing of High Alert Controlled Substances"); Rite_Aid_OMDL_0044361-62 (memo re: "Validation and Dispensing High Alert Controlled Substances"); Rite_Aid_OMDL_0044387 ("Suspicious DEA Pharmacy Activity" memo).

71 Jena, et al. (2011); and Jena and Goldman (2011).

72 Rannazzisi Deposition, p. 197 ("Q. Sir, is it fair that DEA focused its attention in the 2005 to, say, 2009 era on rogue Internet pharmacies? […] A. I would say the -- up until at least 2008, after the Ryan Hate [sic] Act was passed, it pretty much shut down most of the Internet pharmacies and there was a switch to rogue pain clinics. There has always been rogue pain clinics but the rogue pain clinics got -- increased in numbers quite a bit right after Ryan Hate [sic] was passed."); and Rannazzisi Deposition, Exhibit 10.

73 Rannazzisi Deposition, Exhibit 10.

74 "DOJ Prosecutions of Opioid Pill Mills.xlsx" from backup materials to Gruber Report.

involved establishments categorized as a "pharmacy" and only one of these appear to be related to a national chain pharmacy, which was not Rite Aid.[75] The remaining 142 prosecutions were primarily of clinics and medical offices, i.e. pill mills.[76]

4. Rite Aid Mid-Atlantic accounts for less than 1% of opioid distribution in Cuyahoga and Summit Counties

49. Rite Aid Mid-Atlantic distributed a very small share of all opioids into Cuyahoga and Summit Counties. **Exhibit 3** compares the total shipments of opioids to Cuyahoga and Summit Counties with Rite Aid Mid-Atlantic's shipments.[77] Because opioids differ in potency, shipments are measured in MMEs. Throughout the period January 2006 to December 2014, Rite Aid Mid-Atlantic accounted for 0.71 percent of MMEs distributed into Cuyahoga and Summit Counties. Furthermore, and importantly, Rite Aid Mid-Atlantic's share of MMEs distributed into the counties declined over time and eventually fell to **zero** after the rescheduling of HCPs to schedule II in October 2014, since Rite Aid Mid-Atlantic stopped distributing HCPs when they became schedule II and stopped distributing all narcotics in November 2014.[78] In contrast, as I discuss below, MMEs dispensed to these counties from other distributors increased during this period.

---

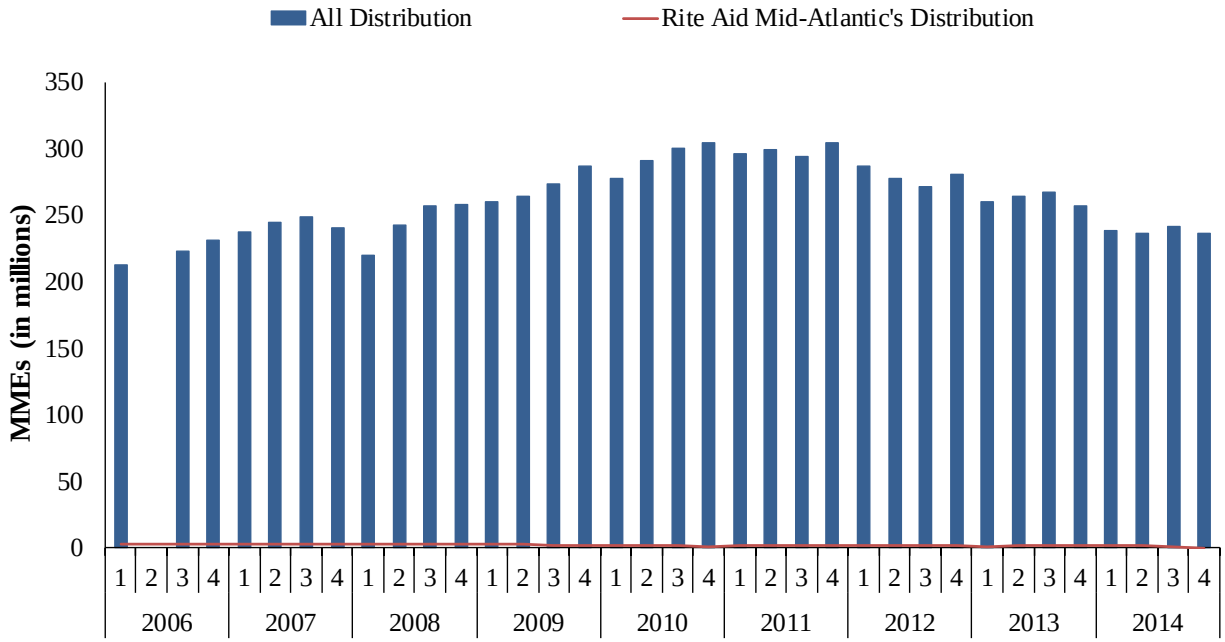
75 The address provided for Eric Tingley is associated with another national chain pharmacy in Connecticut. *Id.*

76 *Id.*

77 *See* ARCOS Data Files. This analysis is limited to observations where the buyer is located in Cuyahoga County or Summit County and the "buyer_bus_act" field is not "ANALYTICAL LAB." Buprenorphine and Methadone are not included in this analysis.

78 ARCOS Data Files; and Rite_Aid_OMDL_0032602.

Exhibit 3
Distribution of Opioid Products to Cuyahoga and Summit Counties



Notes:
[1] This analysis is limited to observations where the buyer is located in Cuyahoga or Summit County, the "transaction_code" is equal to "S" and the "buyer_bus_act" field is not "ANALYTICAL LAB."
[2] Buprenorphine, methadone and non-schedule II codeine are not included in this analysis.
[3] The second quarter of 2006 is not shown because ARCOS data are missing Rite Aid Mid-Atlantic distribution information for May 2006.

Source:
[A] McCann Report (including backup materials).

5. Rite Aid Mid-Atlantic distribution of opioids to Cuyahoga and Summit Counties did not increase like total opioid distribution to Cuyahoga and Summit Counties

50. Dr. Cutler and Dr. Gruber discuss a pattern of increasing opioids shipments nationwide until 2010 in their reports.[79] Dr. Cutler argues that, prior to 2010, "the [opioid] crisis was characterized by large and on-going increases in the shipments of prescription opioids and the rapid increases in mortality associated with prescription opioids."[80] Even though increases in total shipments of prescription opioids do not imply increased diversion, I note the important point that Rite Aid Mid-Atlantic's distribution of opioids into Cuyahoga and Summit Counties

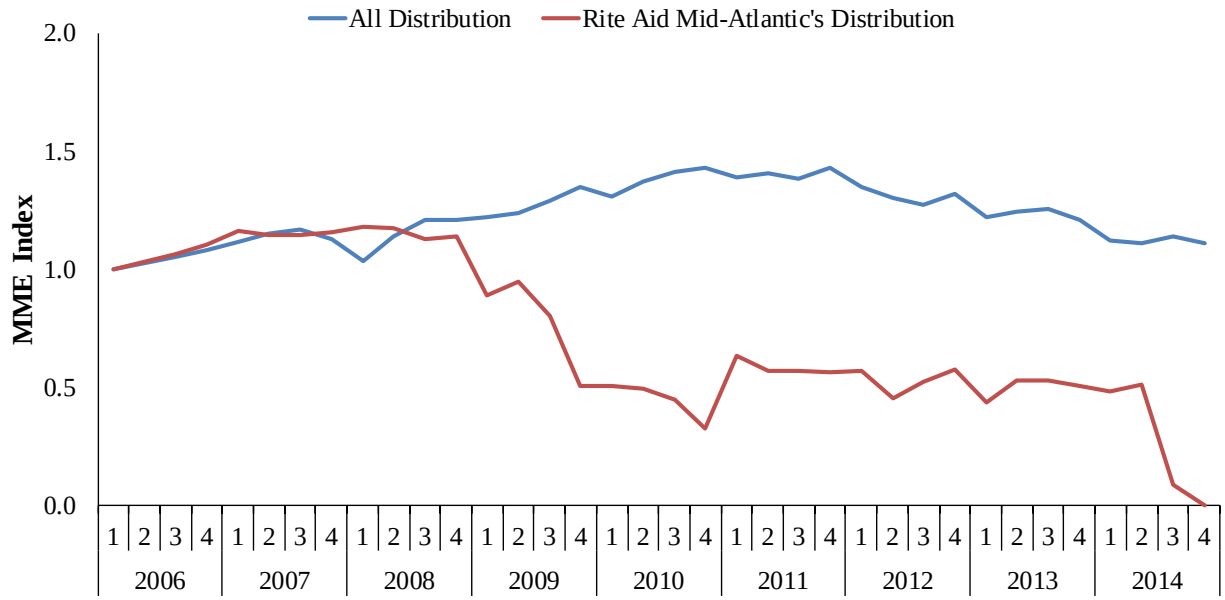
[79] Cutler Report, Section V.A.; and Gruber Report, Section III.
[80] Cutler Report, ¶ 50.

did not follow the same increasing pattern as the total distribution of opioids into Cuyahoga and Summit Counties.

51. **Exhibit 4** compares Rite Aid Mid-Atlantic's distribution of opioids to Cuyahoga and Summit Counties to the total distribution of opioids to these counties for the period 2006 through 2014.[81] To allow for comparison of the trends in distribution, total volume of opioids is calculated as MMEs indexed to the first quarter of 2006. The exhibit shows that Rite Aid Mid-Atlantic's distribution tracks the total distribution through the second quarter of 2008, but then significantly decreases, falling to zero after the rescheduling of HCPs to schedule II in October 2014, when Rite Aid Mid-Atlantic ceased distributing the opioids at issue in this litigation (and only one month prior to when Rite Aid Mid-Atlantic ceased distribution of *all* narcotics in November 2014).[82]

[81] This period corresponds with the data available in the ARCOS Data Files.
[82] ARCOS Data Files; and Rite_Aid_OMDL_0032602.

Exhibit 4
Distribution of Opioid Products to Cuyahoga and Summit Counties

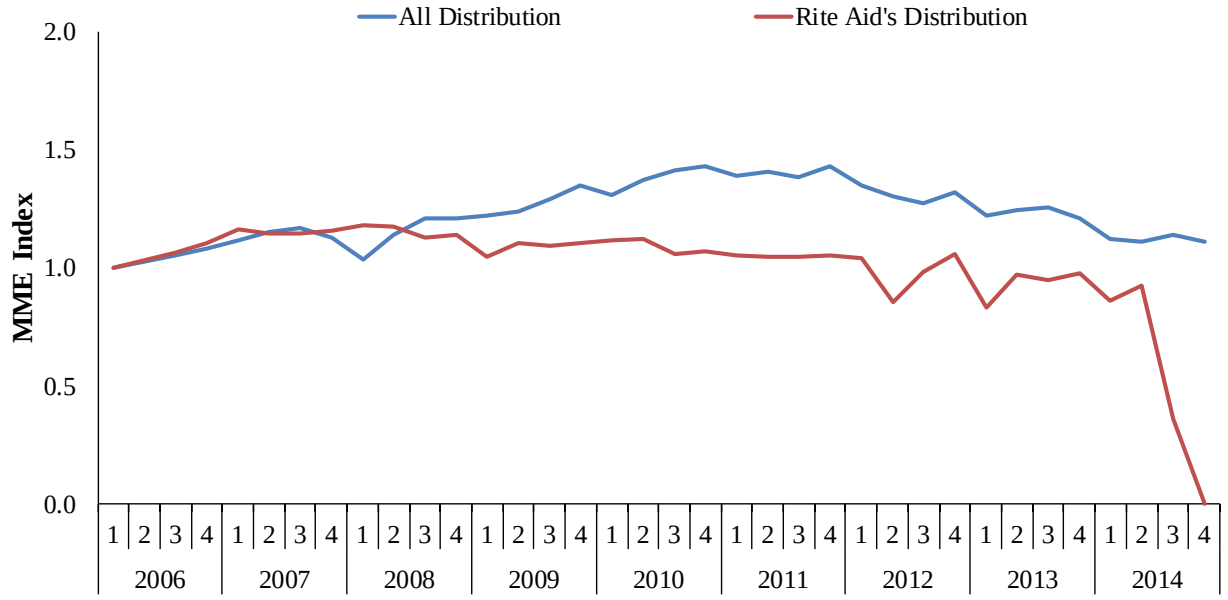


Notes:
[1] This analysis is limited to observations where the buyer is located in Cuyahoga or Summit County, the "transaction_code" is equal to "S" and the "buyer_bus_act" field is not "ANALYTICAL LAB."
[2] Buprenorphine, methadone, and non-schedule II codeine are not included in this analysis.
[3] The MME Index is calculated by dividing the total distribution in MMEs each quarter by the 2006 first quarter distribution in MMEs.
[4] The ARCOS data are missing Rite Aid Mid-Atlantic distribution information for May 2006.

Source:
[A] McCann Report (including backup materials).

52. The decrease in Rite Aid Mid-Atlantic's distribution of opioids into Cuyahoga and Summit Counties in part reflects a general shift in distribution from Rite Aid Mid-Atlantic to another Rite Aid distribution center that I understand is not a defendant in this litigation. To account for this shift, **Exhibit 5** compares the sum of Rite Aid's distribution of opioids to Cuyahoga and Summit Counties to the total distribution of opioids to these counties. While the combined Rite Aid shipments of opioids do not significantly fall after the second quarter of 2008, they do not grow as they do for overall distribution and instead fall or stay flat through 2014, when Rite Aid Mid-Atlantic ceased distributing the opioids at issue in this litigation.

Exhibit 5
Distribution of Opioid Products to Cuyahoga and Summit Counties



Notes:
[1] This analysis is limited to observations where the buyer is located in Cuyahoga or Summit County, the "transaction_code" is equal to "S" and the "buyer_bus_act" field is not "ANALYTICAL LAB."
[2] Buprenorphine, methadone, and non-schedule II codeine are not included in this analysis.
[3] The MME Index is calculated by dividing the total distribution in MMEs each quarter by the 2006 first quarter distribution in MMEs.
[4] The ARCOS data are missing Rite Aid Mid-Atlantic distribution information for May 2006.

Source:
[A] McCann Report (including backup materials).
[B] "Distribution Centers / Ship-to-Locations," *Rite Aid Corporation*, available at http://www.riteaidediservices.com/wp-content/uploads/2018/02/DISTRIBUTION-CENTERS-SHIP%E2%80%93TO-LOCATIONS-Update-20180124.pdf, accessed May 7, 2019.

V. PLAINTIFFS' METHODOLOGY FOR IDENTIFYING SUSPICIOUS ORDERS IS FLAWED AND UNRELIABLE

53. In section IX of his report, titled "Transaction Analysis," Dr. McCann "implemented various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014."[83] In his report, Dr. McCann does not identify these transactions as "suspicious orders," but James Rafalski, Plaintiffs' expert on statutory and regulatory compliance, stated that he "review[ed] five suspicious order methodologies" that "are

[83] McCann Report, ¶ 130.

identified in the McCann Report."[84] Mr. Rafalski states that the "purpose of each system [i.e., methodology] was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion."[85]

54. In this section, I describe the numerous flaws in Dr. McCann's proposed approaches for identifying suspicious orders, that is, why these calculations do not reliably identify orders at risk of diversion. I then describe two basic robustness tests, commonly employed by economists, demonstrating that Dr. McCann's calculations are not reliable. Finally, I explain why Dr. McCann's calculation of "excessive shipments" is baseless and nonsensical.[86]

A. Each of Dr. McCann's five approaches for flagging transactions is unreliable as a method for identifying "suspicious" orders

55. Dr. McCann applies five "approaches" to flagging orders. Each of the five approaches is applied to shipments from a distributor to a specific pharmacy, sometimes for different varieties of an at-issue drug.[87] In the case of Rite Aid Mid-Atlantic, this means each of the approaches is applied to shipments of HCPs (the only at-issue drug Rite Aid Mid-Atlantic distributed)[88] from Rite Aid Mid-Atlantic to each of the 43 Rite Aid stores in Cuyahoga and Summit Counties.[89] The approaches are applied separately, not in combination.

56. Under his five methodologies, Dr. McCann's approaches flag as much as 99.3 percent of shipments in Cuyahoga County and 100 percent in Summit County, with the share flagged depending on the approach and how the share of shipments flagged are measured, as seen in **Exhibit 6** below. On its face, a methodology that flags nearly 100 percent of shipments as being potentially suspicious, without any corroboration of diversion, cannot be taken seriously.

---

84 Rafalski Report, pp. 40-41.
85 *Id.*, p. 41.
86 McCann Report, Section X.
87 Dr. McCann excludes buprenorphine and methadone, which are treatment drugs (McCann Report, footnote 54).
88 Dr. McCann incorrectly flags Rite Aid's orders of schedule III codeine, a substance that is beyond the scope of the litigation. Although codeine can be schedule II depending on the dosage, Rite Aid Mid-Atlantic did not distribute any schedule II codeine. ARCOS Data Files and ECF No. 693, p. 3 ("Accordingly, the Special Master RULES as follows. Defendants shall produce discovery related to all opioid products that are or ever were classified as Schedule II under the Controlled Substances Act.").
89 Dr. McCann also proposes an alternative approach in which chain pharmacy distributors, including Rite Aid Mid-Atlantic, should have identified suspicious orders based on all distributors shipping opioids to their customers (McCann Report, ¶ 152). The flaws in Dr. McCann's approaches apply equally to this alternative.

Exhibit 6
Plaintiffs' Estimates of Rite Aid Mid-Atlantic's Flagged Hydrocodone Transactions By Proposed Approach*

		Cuyahoga County	Summit County
[1]	**Maximum Monthly Trailing 6 Month Threshold**	87%	88%
[2]	**2x Trailing 12 Month Average Pharmacy Dosage Units**	19%	66%
[3]	**3x Trailing 12 Month Average Pharmacy Dosage Units**	12%	16%
[4]	**Maximum 8,000 Dosage Units Monthly**	45%	96%
[5]	**Maximum Daily Dosage Units**	99%	100%

Note:
* All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report, Appendix 10, pp. 541, 550, 559, 568, 577, 1171, 1180, 1189, 1198, 1207.

1. "Maximum Monthly, Trailing Six-Month Threshold"

57. Under Dr. McCann's first approach, transactions are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy in a calendar month to exceed the highest number of dosage units shipped in a calendar month by the Distributor to that Pharmacy in the last six months.[90]

58. This approach is highly likely to flag orders that are not at risk of diversion because it does not allow for growth in Rite Aid Mid-Atlantic's distribution volume to each pharmacy. Increases in distribution to a pharmacy occur for many reasons, including: routine month-to-month variation in ordering patterns, variation in the number of deliveries that happen to fall within a calendar month (for example, if a pharmacy receives deliveries every week, most months will have four deliveries but some will have five), the pharmacy could switch distributors or rely on one distributor more than another in a given month, the population could grow where the pharmacy is located, a nearby hospital or clinic could open up, a nearby pharmacy could close down (increasing the volume of that pharmacy), and/or new drugs could be released.

[90] McCann Report, ¶ 131. Under this methodology, Dr. McCann sets a minimum monthly threshold of 1,000 dosage units per calendar month. *See* backup materials to McCann Report, Step1_MaxMonthlyTrailing6M.m.

59. Although Dr. McCann does not choose a preferred methodology, Mr. Rafalski suggests that this method "provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size."[91] But Mr. Rafalski does not explain why Rite Aid Mid-Atlantic's suspicious order monitoring did not meet the relevant regulatory requirements. Furthermore, Mr. Rafalski's opinion that the first method is "an initial trigger" and a "first step" imply that this method is not sufficient on its own.

2. "Twice Trailing Twelve-Month Average Pharmacy Dosage Units"

60. Under Dr. McCann's second approach, transactions are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy in a calendar month to be more than two times the average dosage units shipped to all retail and chain pharmacies served by the distributor in the last 12 months.[92] This approach applies a single monthly threshold across all pharmacies to which Rite Aid Mid-Atlantic distributed.

61. Applying a national average to establish a common threshold for all pharmacies does not make economic sense as a means of identifying suspicious prescription opioid distributions for the obvious reason that pharmacies vary in the size and composition of the populations they serve. A pharmacy serving a large population would be expected to distribute larger quantities of opioids than a pharmacy serving a smaller population during a fixed period of time, all else equal. Similarly, a pharmacy located next to a major hospital or set of large dental clinics would be expected to dispense more opioids than otherwise similar pharmacies. Consistent with this logic, Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, testified that whether an order is identified as suspicious depends on where the customer is situated, for example whether the customer is close to a

---

[91] Rafalski Report, p. 46 ("…it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size. [Footnote: This approach does not take into consideration unusual pattern or frequency.] *See* Methodology A above. Pursuant to *Masters*, 'as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an "unusual" and not "normal" occurrence' *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.").

[92] McCann Report, ¶ 136.

hospital or in a rural area.[93] This makes sense because using a national average to establish a common threshold across all pharmacies will mechanically cause shipments to the pharmacies with the largest volumes of business to be flagged as suspicious, even when the shipments are in line with the pharmacy's historical volume of prescriptions and the medical needs of the local community. This method is therefore not a reliable method for identifying shipments at risk of diversion. Furthermore, using an average that is not pharmacy-specific has been criticized by Plaintiffs' own expert, Matthew Perri.[94]

62. While Dr. McCann appears to have intended to use the national average of Rite Aid Mid-Atlantic's distribution,[95] in practice he used the average for Rite Aid pharmacies in Cuyahoga and Summit Counties rather than the national average.[96] Applying the national average for Rite Aid Mid-Atlantic reduces the percentage of flagged transactions into both Cuyahoga and Summit Counties.[97]

3. "Three Times Trailing Twelve-Month Average Pharmacy Dosage Units"

63. Dr. McCann's third approach is the same as the second approach, but the threshold is raised from twice to three times the average shipment of the past 12 months.[98] As such, all criticisms described in the previous section also apply to this method. As described above, for Rite Aid Mid-Atlantic, Dr. McCann used the average for Rite Aid pharmacies in Cuyahoga and Summit Counties rather than the national average. Applying a national average for Rite Aid Mid-

---

93 Rannazzisi Deposition, pp. 274-275 ("Q. It's a business decision as to whether something is a suspicious order as well, correct? A. Yes. Q. And it may be that one business faced with a particular order makes a different decision on the exact same order than another business, correct? […] A. It depends on the type of due diligence they're doing on their customers; whether they know their customers and what their customers' normal ordering patterns are; where is their customer situated; is the customer close to a hospital; is the customer close to -- is in a rural area. There's so many dynamics that the drug enforcement administration doesn't have. Only the business, the distributor, the registrant has that information.")

94 "In my opinion, the Pro Compliance report does not correctly assess the appropriateness of dispensing of controlled substances at Cherokee Pharmacy for the following reasons: The Pro Compliance report provides statistics on drug utilization that incorrectly compares the data from Cherokee Pharmacy to national averages, not similar pharmacy businesses." Expert Report of Matthew Perri III, *In the United States District Court for the District of South Carolina Spartanburg Division, JM Smith Corporation v. Cherokee Pharmacy and Medical Supply, Inc., et al.,* August 6, 2014, ¶ 31.

95 Second Supplemental Expert Report of Craig J. McCann, April 15, 2019, footnote 13 ("In the McCann Report, I reported the result of comparing transactions with Dispensers to two times, and three times, transactions with similar pharmacies nationally.").

96 McCann Report backup, Step0_Find_12M_USA_Avg.m; and CHM_AveX3_DU.xlsx.

97 *See* backup materials.

98 McCann Report, ¶ 140.

Atlantic reduces the percentage of flagged transactions into both Cuyahoga and Summit Counties. For example, applying a national average reduces the percent of flagged Rite Aid Mid-Atlantic transactions into the Cuyahoga County by almost 50 percent (from 12.2 percent to 6.5 percent).[99] Since the thresholds in this methodology are higher than those in method 2, the percent of flagged Rite Aid Mid-Atlantic transactions are lower.

4. "Maximum 8,000 Dosage Units Monthly"

64. Under Dr. McCann's fourth approach, transactions are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy to exceed 8,000 dosage units in a calendar month.[100] In other words, it is presumptively suspicious for any pharmacy, *regardless of its size*, to receive shipments of more than 8,000 dosage units in a calendar month.

65. As with Dr. McCann's second and third approaches, this approach applies a common monthly threshold across pharmacies, ignoring any variation in the size and composition of the populations the pharmacies serve.

66. Dr. McCann provides no source for the 8,000 dosage unit threshold, but I understand this methodology appears in a McKesson document that outlines this as a McKesson-specific threshold as part of its "Lifestyle Drug Monitoring Program."[101] As described to the DEA, McKesson's "Lifestyle Drug Monitoring Program" excluded national chain pharmacy accounts, including Rite Aid, because the DEA had not identified any issues with those accounts.[102]

67. Although Rite Aid Mid-Atlantic implemented a threshold that was common across stores as part of its suspicious order monitoring measures, it differed in important ways from the

---

99 *See* backup materials.

100 McCann Report, ¶ 144.

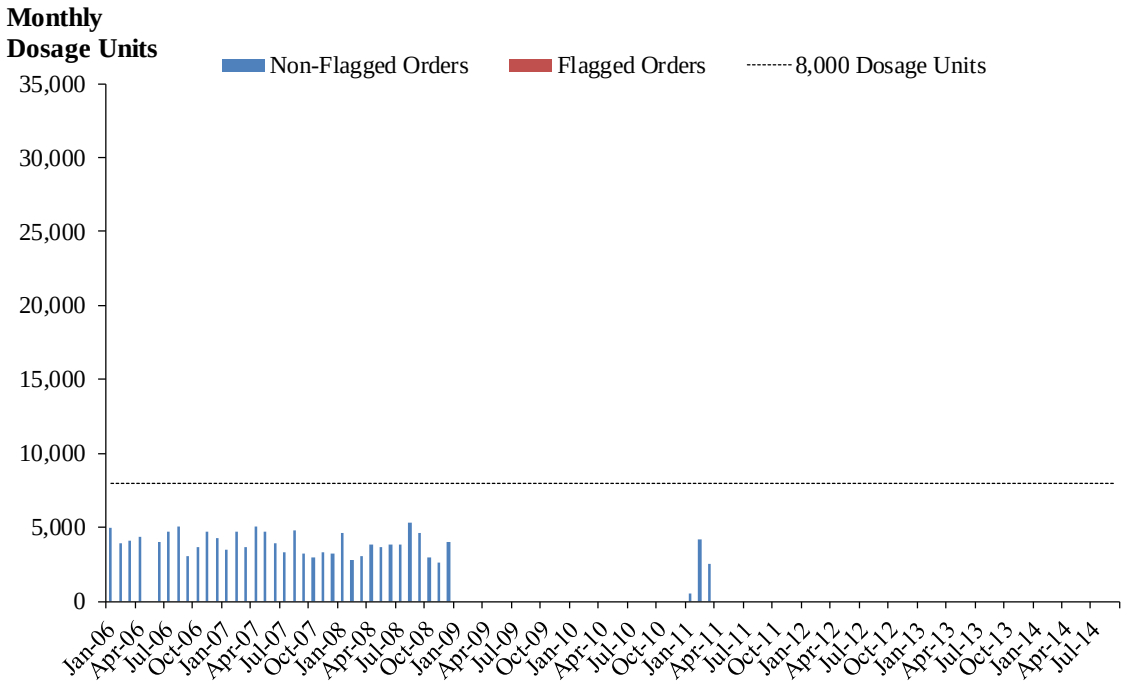
101 "The report will summarize customers who have purchased quantities of all products containing the identified base code in excess of the threshold for the item. For example all sales and credits of Mckesson items containing Hydrocodone will be added together and reported if the total doses exceeded 8,000 unit." 1_MCKMDL00355041_image.pdf at 355042.

102 Deposition of Nathan J. Hartle, Vice President of Regulatory Affairs and Compliance for McKesson Corporation, July 31-August 1, 2018, Exhibit 17 (stating that "[w]hen a pharmacy customer appears on the report for the first time (because they have met or are about to exceed 8,000 dosage units for the month) the DC will review the orders to determine whether it is justified based on the type of customer, e.g., **national chain account**, and the historical purchases by the customer" and observing that "McKesson currently has a number of contractual commitments with large pharmacy chain customers such as … Rite Aid. None of these customers is a source of the problem identified by DEA involving dispensing of lifestyle drugs without appropriate prescriptions." (emphasis added)).

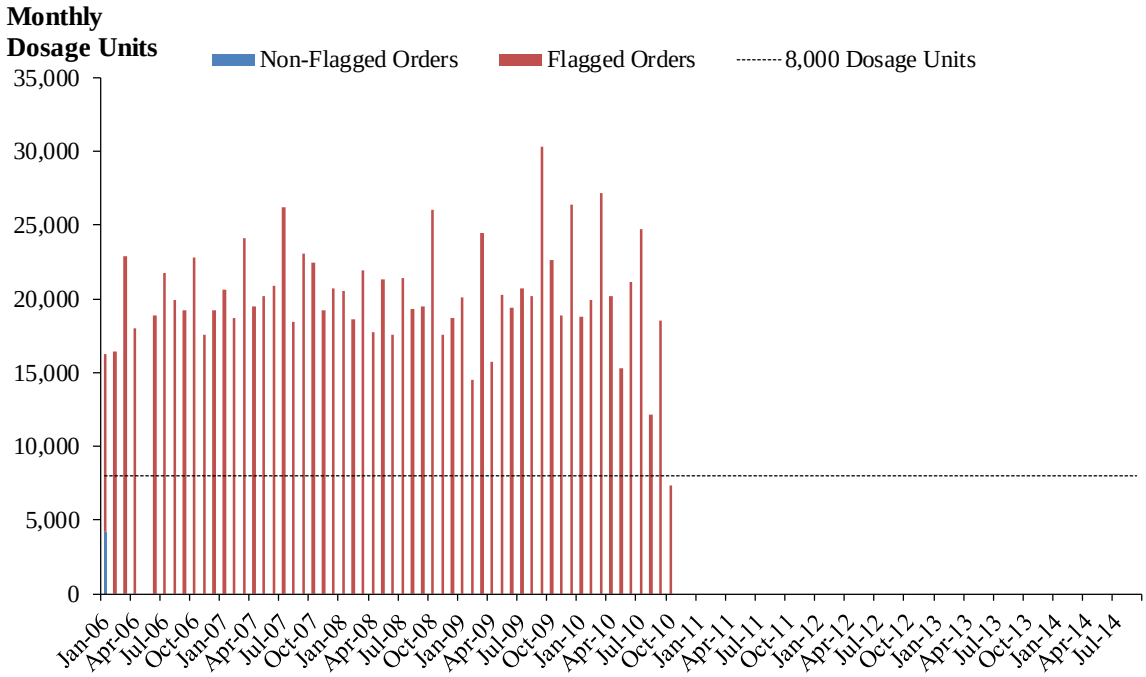
threshold implemented by Dr. McCann. In particular, as I described in section IV.A: (1) quantities in excess of the threshold were not shipped; (2) the threshold was implemented per order, not per month, with a set frequency for orders that varied by store; (3) individual stores could be granted exceptions to the default threshold of 5,000 dosage units per order if an evaluation found that they merited a higher limit; (4) orders over the limits were investigated, as demonstrated by threshold logs; and (5) these limits were not the sole method for preventing diversion. These differences allow for variation in the threshold across pharmacies due to differences in their size, avoiding the flaws in Dr. McCann's approach.

68. The inappropriateness of using such a blanket rule as the method for identifying suspicious orders should be obvious when dealing with pharmacies of varying size, but the flaw can also be readily seen by comparing the results Dr. McCann obtained for Rite Aid Mid-Atlantic's distribution of HCPs to two different pharmacies of differing size. **Exhibit 7** shows flagged shipments to stores #4788 and #3157 using the 8,000 dosage unit monthly threshold.

Exhibit 7
Methodology: Maximum 8,000 Dosage Units Monthly
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #4788



Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #3157



Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

69. Rite Aid store #4788 was on the outskirts of Cleveland. It was more than 4.5 miles' drive from all major hospitals and was closed in February 2019.[103] It received monthly shipments far below the 8,000 dosage unit threshold, so no transactions were ever flagged. In contrast, Rite Aid store #3157 is close to downtown Cleveland, about one mile from a hospital, and open 24 hours a day, seven days a week. This store received shipments from Rite Aid Mid-Atlantic that exceeded 8,000 monthly dosage units in *every month* they shipped from January 2006 on, except for October 2010, which is the last month Rite Aid Mid-Atlantic shipped HCPs to that store. In most months, shipments were over 15,000 dosage units. As such, Dr. McCann flags 1,851 out of 1,861 transactions, or 99.5 percent of transactions. Given the differences in these two pharmacies, it does not make sense for Rite Aid Mid-Atlantic, nor Dr. McCann, to assume that virtually all shipments to the second store are suspicious due to the shipment size alone. Due to the size of store #3157, shipments in excess of 8,000 dosage units in a month are not inherently suspicious.

5. "Maximum Daily Dosage Units"

70. Dr. McCann's fifth approach is similar to the fourth approach, but with a daily rather than monthly threshold. For hydrocodone products, transactions are flagged if more than 800 dosage units are shipped from the distributor to that pharmacy on a given day.[104] In other words, it is presumptively suspicious for any pharmacy, *again regardless of its size*, to receive shipments of more than 800 dosage units of hydrocodone on any given day.

71. To justify this daily threshold methodology, Dr. McCann cites to a Cardinal Health document.[105] Cardinal noted that the "dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items."[106] There is nothing in the document to suggest that these thresholds would be applicable to other distributors with different business practices. Dr. McCann neither explains why this threshold should apply to all distributors throughout the years analyzed nor does he consider whether pharmacies that

---

[103] Property listing for 7109 Harvard Avenue, Cleveland, Ohio 44105, available at https://www.crexi.com/properties/210808/ohio-rite-aid-dark, accessed May 2, 2019.
[104] McCann Report, ¶ 148.
[105] *Id.*, footnote 55.
[106] CAH_MDL_PRIORPROD_DEA07_01383895-R - 01384238-R at 1383940-R.

treat larger patient populations should appropriately be more likely to exceed daily dosage thresholds. For the reasons explained above, a threshold that fails to account for variation across pharmacies in patient population and composition will be unreliable in flagging orders at risk for diversion.

72. Similar to the McKesson Maximum 8,000 Dosage Units Monthly threshold (approach 4), this methodology was created for Cardinal Health and not for Rite Aid Mid-Atlantic. Dr. McCann applies this to all distributors, disregarding the fact that DEA agents have testified to the necessity of a SOM that is unique for each distributor.[107] In addition to the other flaws in this approach, it does not make sense to use a daily threshold that ignores the frequency of shipments. This is especially relevant for Rite Aid. During this time period, all Rite Aid pharmacies in Cuyahoga and Summit Counties received shipments from Rite Aid distributors on average, once a week or less.[108] All else equal, this method will tend to flag orders to stores that receive less frequent shipments. For example, suppose pharmacy A and pharmacy B both order 1,000 dosage units per week. If pharmacy A orders 500 dosage units twice a week, Dr. McCann's methodology would never flag any orders to this pharmacy, because no order exceeded 800 dosage units. If pharmacy B ordered 1,000 dosage units once a week, every dosage unit would be flagged.

73. Perhaps most remarkable is the percentage of transactions that Dr. McCann flags when he applies this method. As seen above in **Exhibit 6**, Dr. McCann's maximum daily dosage unit method flags *99 percent* and *100 percent* of HCP transactions Rite Aid Mid-Atlantic distributed into Cuyahoga and Summit Counties, respectively. As such, Dr. McCann's

---

[107] Prevoznik Deposition, p. 446 ("Q. Is it fair to say that a SOMs systems is not a one-size-all proposition, one-size-fits-all proposition? A. Correct. […] Q. And DEA expects that each registrant will review its own business model and design a SOM system that fits its specific method of distribution? […] A. That's correct as -- as per the regulations."); Wright Deposition, pp. 128-129 ("Q. And it was understood, with the move toward the Suspicious Order Monitoring Program, that not every company would necessarily have the exact same type of program; fair? […] A. Yes, ma'am. Q. And, in fact, DEA wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might serve, correct? […] A. Yes ma'am."); and Rannazzisi Deposition, p. 321 ("Q. So how does a registrant know that their system is enough that its compliant with the regulations? […] A. Because the regs tell them that they must design and operate a system that identifies suspicious orders and they have to report. How they create that system is a business decision and as long as it identifies and reports suspicious orders, then -- and they are comfortable with that system, then they have a system.").

[108] Since the ARCOS data are missing Rite Aid distribution information for May 2006, this analysis calculates the average number of days in a week with a shipment from June 2006 to September 2014. *See* backup materials.

approach here would suggest that effectively *all* opioid prescriptions being filled in Cuyahoga and Summit Counties at Rite Aid pharmacies were suspicious. A *complete* cessation of opioid dispensation by a distributor to a pharmacy, as Dr. McCann insinuates should have occurred using this suspicious ordering threshold, could have significant adverse clinical implications as patients with legitimate medical needs would be denied access to treatment options. All of this goes to illustrate the completely nonsensical nature of his method.

B. Dr. McCann's "Transaction Analysis" is unsupported and does not reliably identify orders associated with diversion

74. Dr. McCann provides no support for his methodologies and calculations. He does not say why he implemented these five methods. Dr. McCann cites to no academic or industry sources to justify his calculations. In my expertise, they are not justified and lack a theoretical grounding.

75. Notably, Dr. McCann does not describe his calculations as a method for identifying suspicious orders, but as "various approaches to identify transactions meeting specified criteria."[109] Mr. Rafalski states that "some of [Dr. McCann's five methodologies] were utilized by one or more of the defendants" but he does not state which methodology or defendant used any of these methods.[110] And he provides no basis to apply any of them to Rite Aid Mid-Atlantic.

76. In addition, neither Dr. McCann, nor any other expert, demonstrate that the orders flagged by his approaches were associated with diversion. In my opinion as an economist, physician, and health policy researcher, identifying opioid transactions as being suspicious is a non-trivial empirical exercise and one that, at a minimum, must explicitly demonstrate why the allegedly suspicious transactions reflect diversion. For example, were specific Rite Aid Mid-Atlantic flagged transactions linked to evidence that Rite Aid Mid-Atlantic did not have sufficient controls against opioid diversion? As I discuss below, Dr. McCann's approach to flagging purportedly suspicious opioid transactions does not address these issues and, as a result, he identifies implausibly high rates of purportedly suspicious opioid transactions.

[109] McCann Report, ¶ 130.
[110] Rafalski Report, pp. 40-41.

C. The assumption that all shipments after the first flagged transaction should also be flagged is baseless and makes no sense

77. For each methodology, Dr. McCann states the he was instructed to "assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[111] For example, in each approach, once one shipment of HCPs from Rite Aid Mid-Atlantic to Store #3155 was flagged, *all* subsequent shipments of HCPs were flagged.[112] I refer to this as Dr. McCann's "all-subsequent-shipments-are-tainted" assumption.

78. A single order that meets the criteria for being "suspicious" provides no reason to conclude that all future orders that do not meet the same criteria are also "suspicious" and likely to be diverted.[113] For example, if a pharmacy consistently dispenses an average of 10 doses of hydrocodone a week, an order consistent with a dispensing rate of 100 doses per week might be suspicious, but if all subsequent orders are consistent with the pharmacy's 10 dose per week dispensing rate, in my opinion, each of the subsequent orders is not more likely to be diverted than the others, although the single aberrant 100 dose distribution possibly could be.

79. This highly unwarranted assumption has an enormous effect on the share of Rite Aid Mid-Atlantic transactions flagged by Dr. McCann's methodologies (and therefore a large effect on the results of all of the experts who rely on his results). For example, under Dr. McCann's first approach, orders are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy in a calendar month to exceed the highest number of dosage units shipped in a calendar month by the Distributor to that Pharmacy in the last six months. As shown in

---

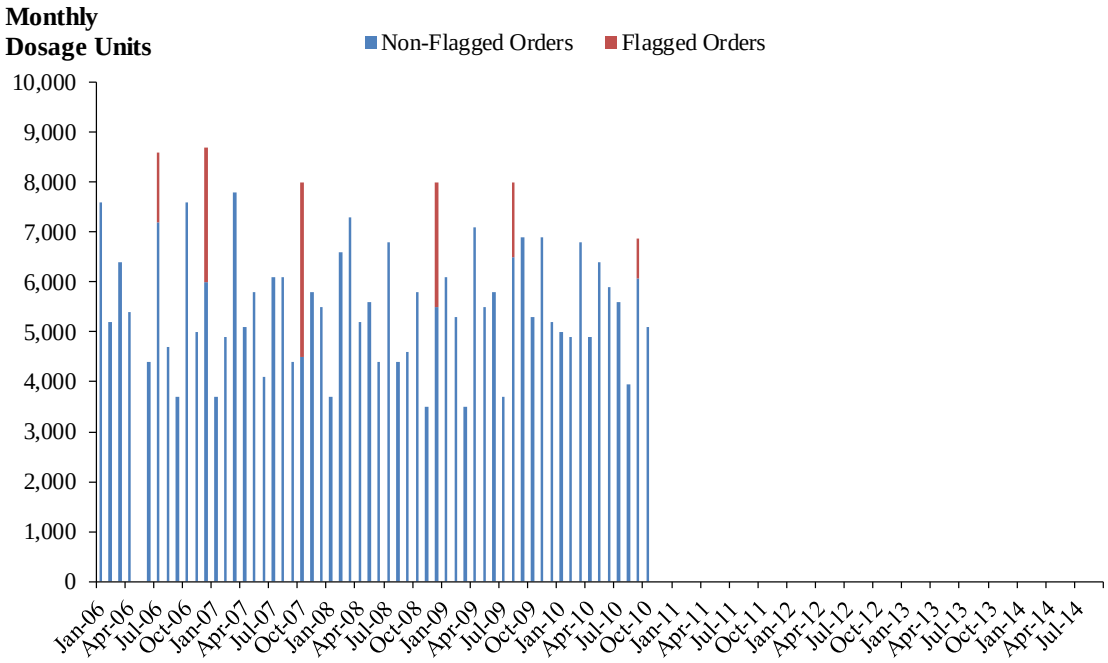
111 McCann Report, ¶ 132.

112 In addition, if any order on a day causes the dosage units to exceed Dr. McCann's calculated threshold, he considers all the dosage units on that day to be suspicious, not just the portion that pushes it above the threshold.

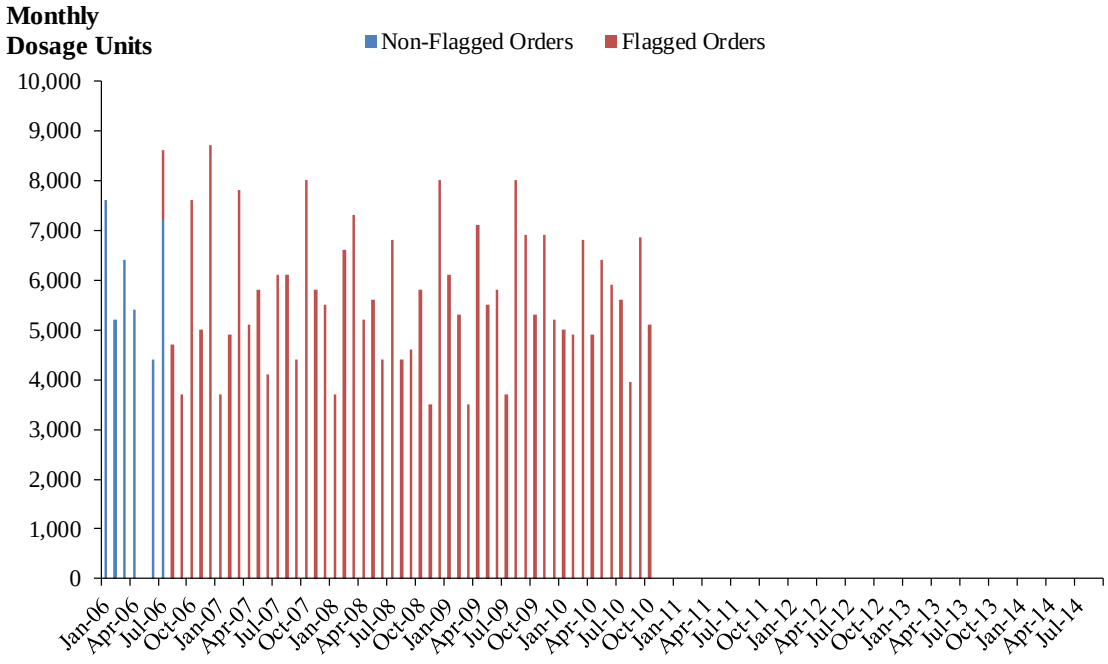
113 This assumption is further contradicted by Rite Aid's suspicious order monitoring system. I have seen no analysis put forward by any other of Plaintiffs' experts to justify the assumption that Rite Aid Mid-Atlantic did not effectively investigate flagged transactions associated with diversion. In fact, the "threshold logs" produced by Rite Aid are evidence that orders Rite Aid identified as potentially suspicious were investigated, with various outcomes depending on their findings. Even if, contrary to my findings, there were evidence that a potentially suspicious order for HCPs from Rite Aid Mid-Atlantic to a particular store was not effectively investigated, it makes no sense to assume that all future orders are necessarily suspicious or in some way "tainted." First, it may be that further investigation would have found the order not suspicious. Considering the various measures Rite Aid Mid-Atlantic maintained for monitoring and preventing diversion that is likely to be the case. It is even more likely to be true given the arbitrary thresholds set by Dr. McCann.

Exhibit 8, there were six months where Rite Aid Mid-Atlantic's shipments of HCPs to Rite Aid Store #3155 exceeded the maximum monthly trailing six-month threshold. This results in 4 percent of shipments being flagged. But with the all-subsequent-shipments-are-tainted assumption, Dr. McCann flags *every shipment* after July 2006, resulting in 89 percent of shipments being flagged. Similarly, **Exhibits 9** to **12** provide examples for the other four methodologies applied by Dr. McCann.

Exhibit 8
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #3155
Methodology: Maximum Monthly, Trailing Six-Month Threshold
Without All-Subsequent-Shipments-Are-Tainted Assumption



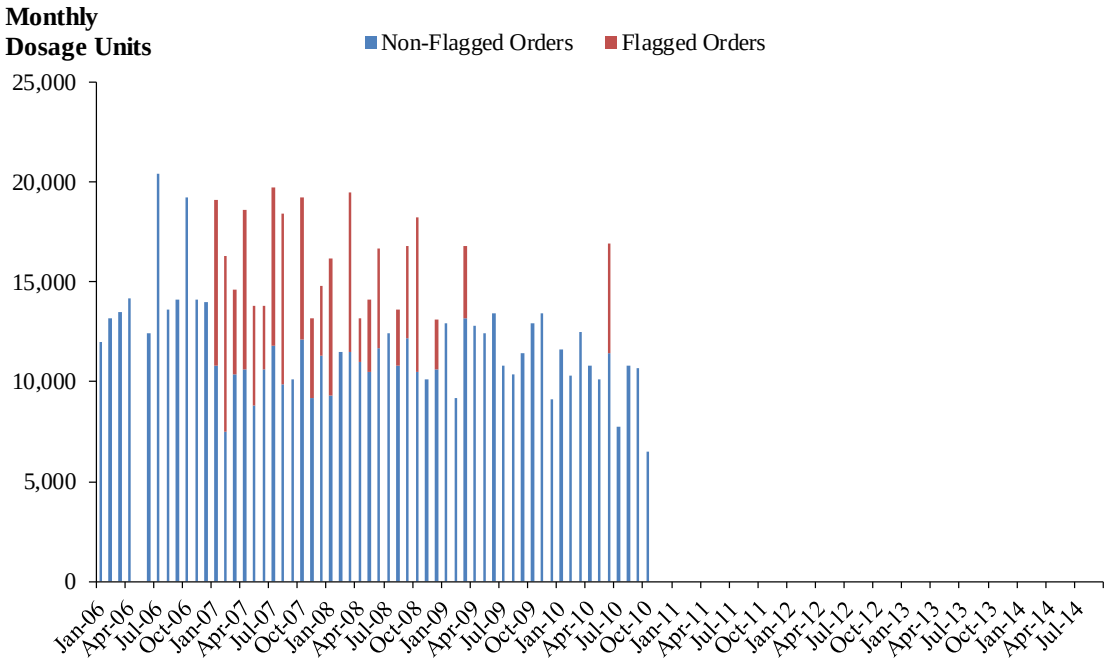
With All-Subsequent-Shipments-Are-Tainted Assumption



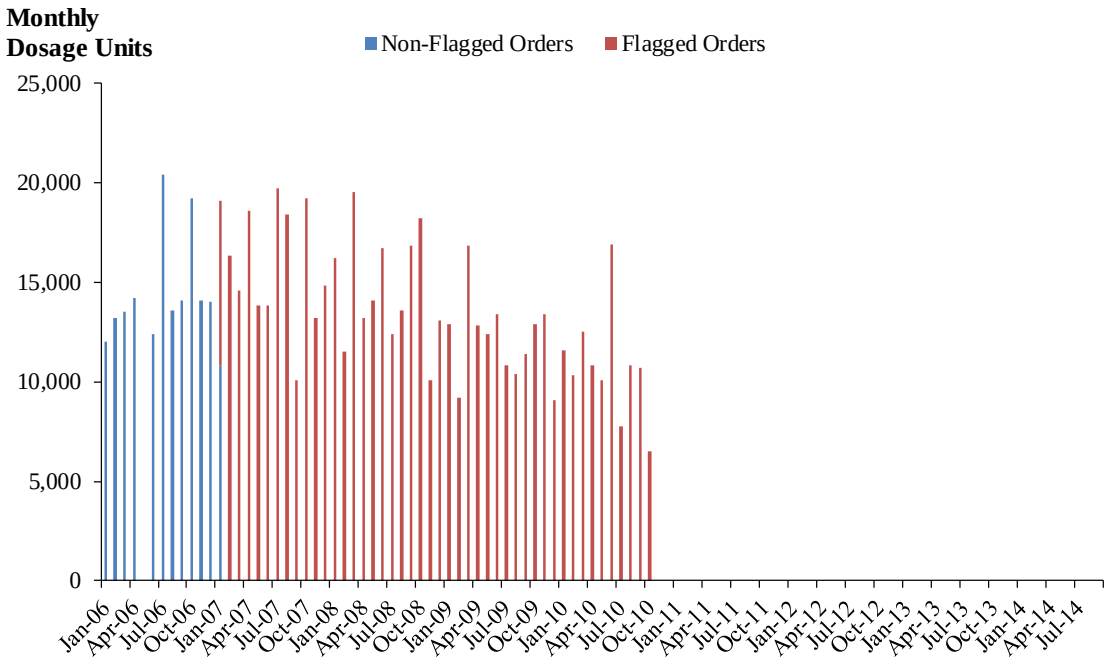
Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

Exhibit 9
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #3053
Methodology: Twice Trailing 12-Month Average Pharmacy Dosage Units
Without All-Subsequent-Shipments-Are-Tainted Assumption



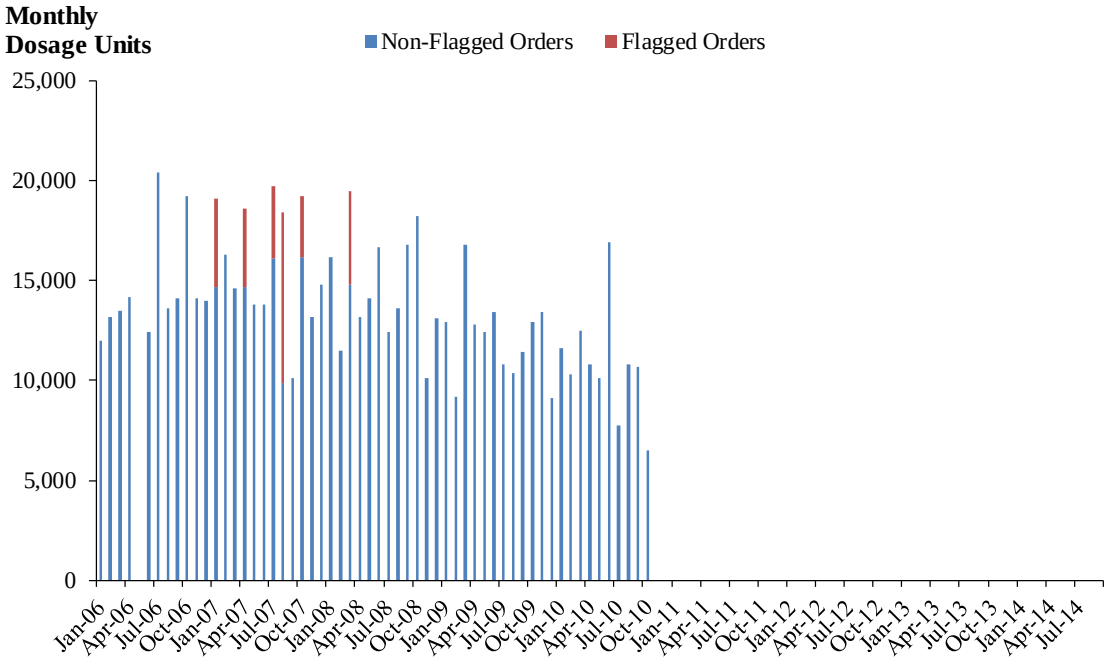
With All-Subsequent-Shipments-Are-Tainted Assumption



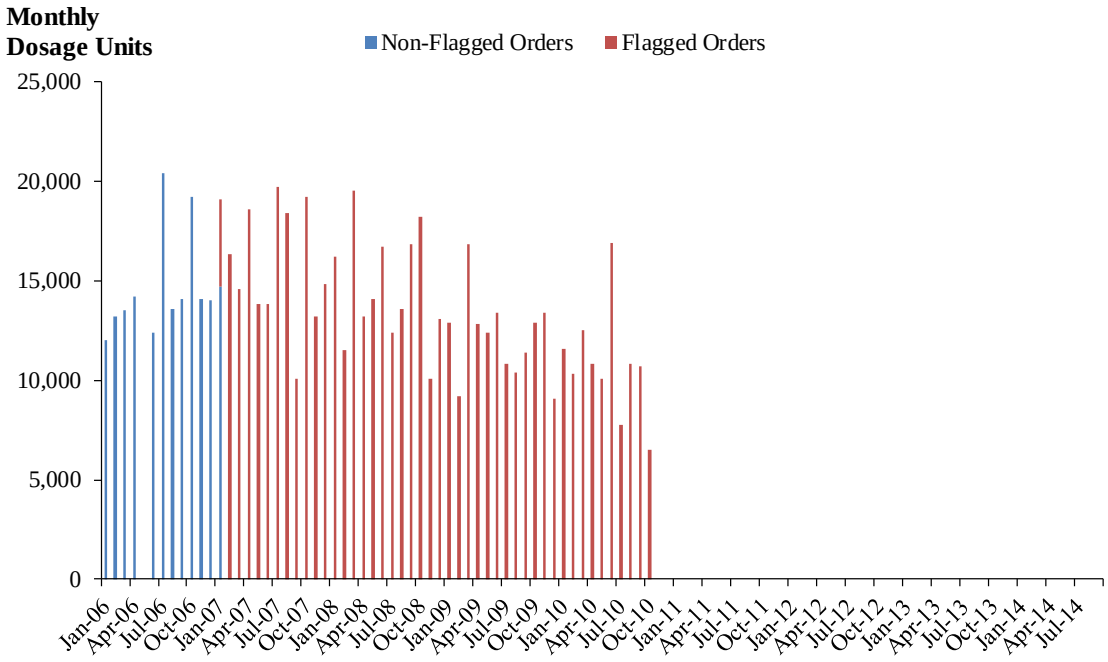
Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

Exhibit 10
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #3053
Methodology: 3x Trailing 12-Month Average Pharmacy Dosage Units
Without All-Subsequent-Shipments-Are-Tainted Assumption



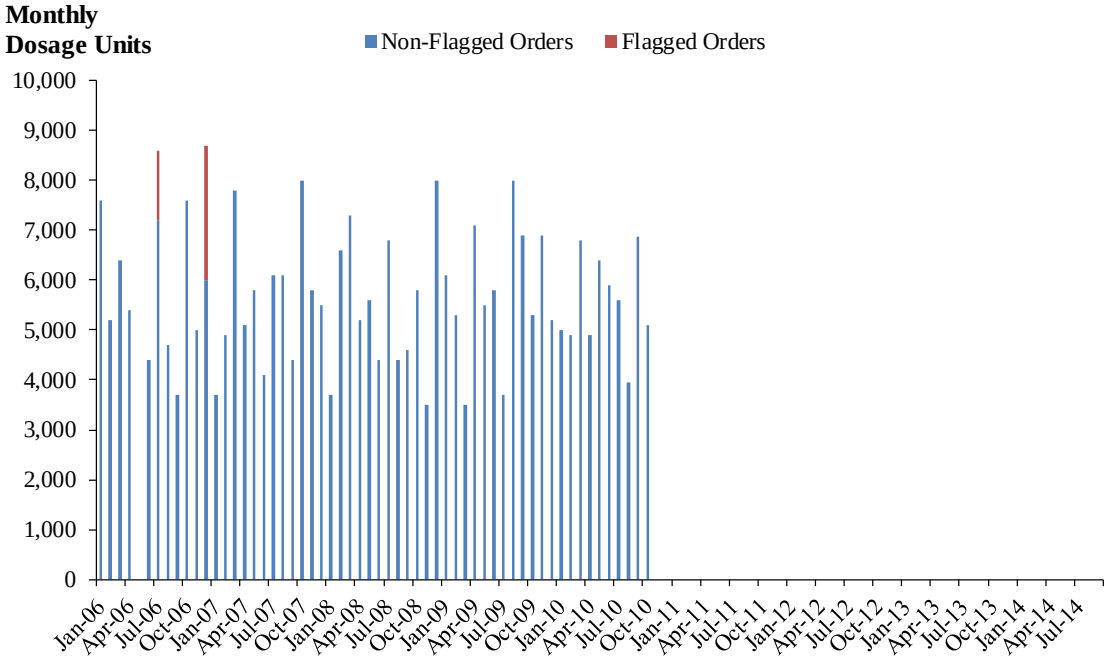
With All-Subsequent-Shipments-Are-Tainted Assumption



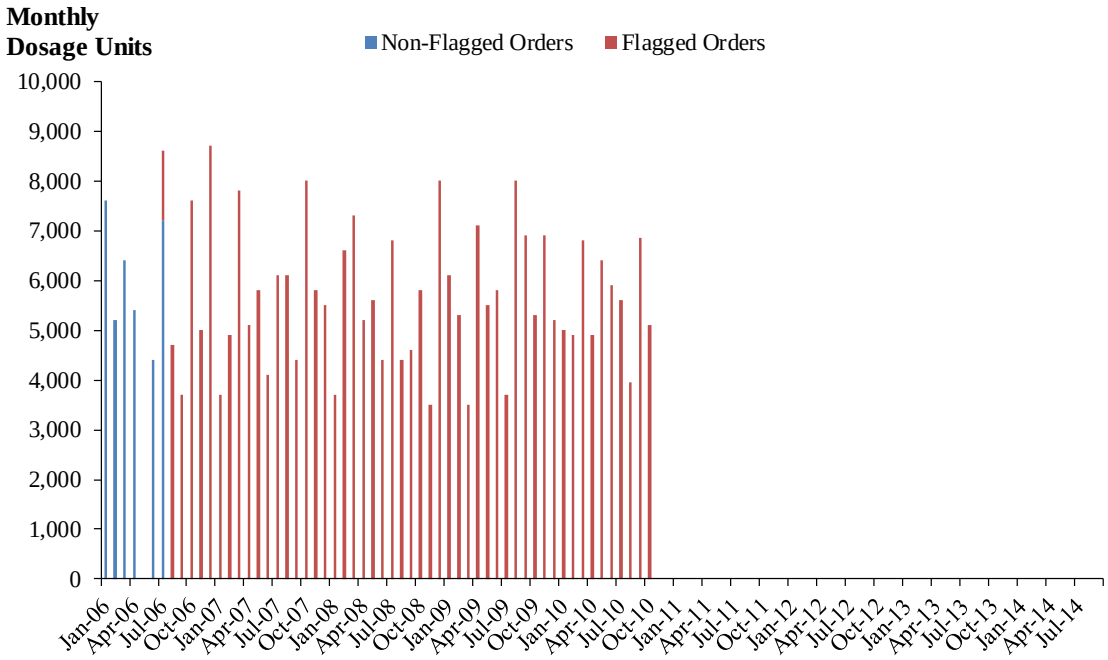
Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

Exhibit 11
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #3155
Methodology: Maximum 8,000 Dosage Units Monthly
Without All-Subsequent-Shipments-Are-Tainted Assumption



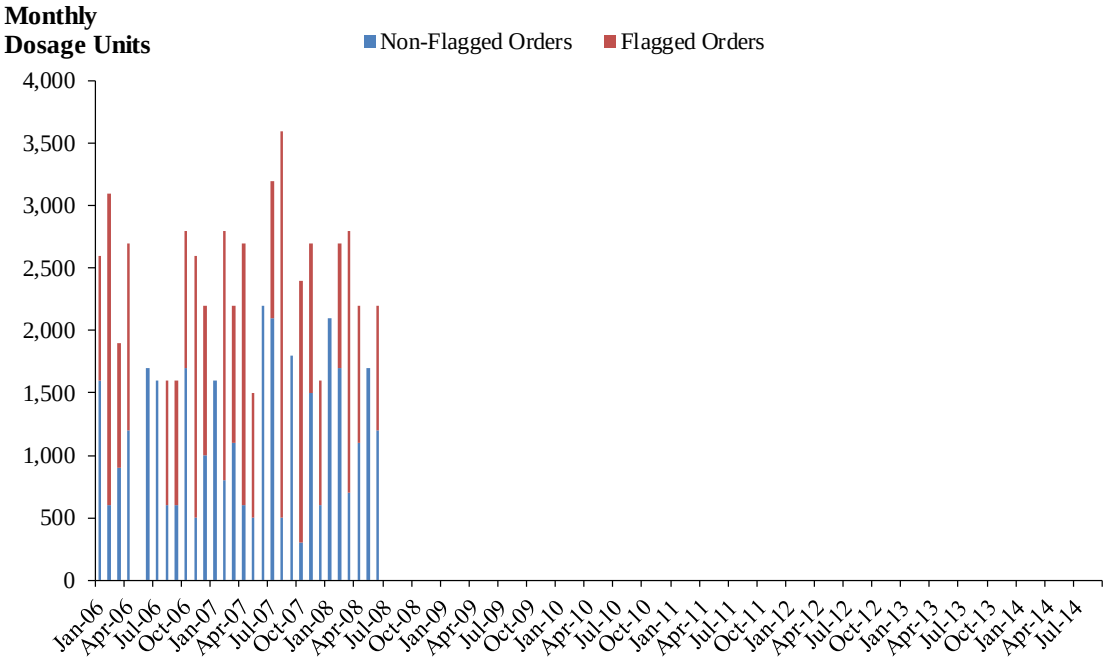
With All-Subsequent-Shipments-Are-Tainted Assumption



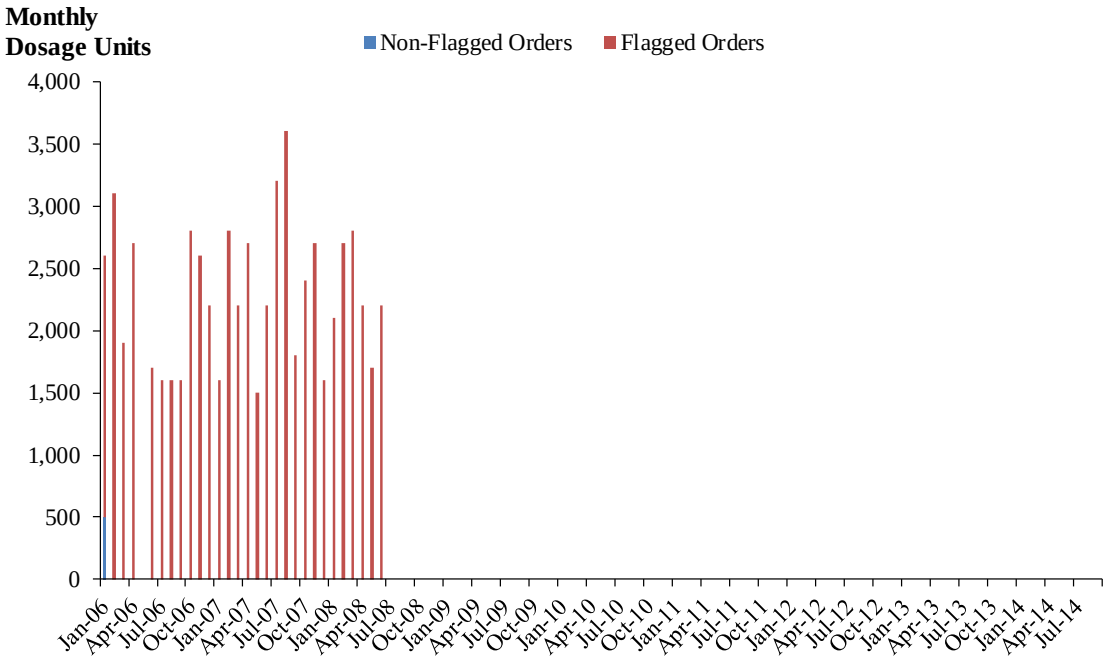
Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

Exhibit 12
Distribution of Hydrocodone by Rite Aid Mid-Atlantic to Rite Aid Store #1100
Methodology: Maximum Daily Dosage Units
Without All-Subsequent-Shipments-Are-Tainted Assumption



With All-Subsequent-Shipments-Are-Tainted Assumption



Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

80. To further demonstrate the enormous impact of this erroneous assumption on Dr. McCann's results, and therefore other experts' opinions, **Exhibit 13** shows the number of Rite Aid Mid-Atlantic transactions to Cuyahoga and Summit Counties flagged by Dr. McCann's approaches both with and without the all-subsequent-shipments-are-tainted assumption. My conclusion from this analysis is that it is scientifically inaccurate to allege that all subsequent opioid shipments following a flagged shipment should also be identified as suspicious. Whether intended or not, such an approach leads to estimates of suspicious opioid distribution that markedly overstate any potential problems that pharmacies may have had. A more realistic accounting that identifies outlier shipments only, as opposed to all non-outlier but following shipments, would place rates of potential suspicious opioid shipments many times below what Dr. McCann's methodology asserts.

81. Perhaps the most important criticism of Dr. McCann's all-subsequent-shipments-are-tainted assumption is that it essentially argues that *none* of the opioid prescriptions distributed subsequent to a flagged transaction could reflect legitimate prescriptions for patients who may benefit from opioids. Put differently, if Rite Aid Mid-Atlantic were to have acted on the basis of Dr. McCann's suspicious order methodology, or a similar methodology, a significant number of patients with legitimate pain needs would be potentially unable to fill prescriptions for opioids at a Rite Aid pharmacy located in Cuyahoga or Summit Counties. A methodology that lacks the ability to accurately separate appropriate opioid use from outright diversion is not a reliable or useful methodology.

Exhibit 13
Plaintiffs' Estimates of Rite Aid Mid-Atlantic's Flagged Hydrocodone Transactions With and Without All-Subsequent-Shipments-Are-Tainted Assumption

		Cuyahoga County, Ohio		Summit County, Ohio	
		With Subsequent-Shipment Assumption	Without Subsequent-Shipment Assumption	With Subsequent-Shipment Assumption	Without Subsequent-Shipment Assumption
[1]	Maximum Monthly Trailing Six-Month Threshold	87%	5%	88%	5%
[2]	2x Trailing 12 Month Average Pharmacy Dosage Units	19%	4%	66%	11%
[3]	3x Trailing 12 Month Average Pharmacy Dosage Units	12%	1%	16%	2%
[4]	Maximum 8,000 Dosage Units Monthly	45%	15%	96%	40%
[5]	Maximum Daily Dosage Units	99%	72%	100%	97%

Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

D. Even under Dr. McCann's flawed approach, Rite Aid Mid-Atlantic's allegedly suspicious shipments account for a *de minimis* share of opioids distributed to Cuyahoga and Summit Counties

82. In this section, I have explained why none of Dr. McCann's approaches are a reliable basis for identifying orders at risk of diversion. Even if one accepted that Dr. McCann's methods are valid approaches for flagging potentially suspicious orders, the share of opioids distributed to Cuyahoga and Summit Counties that are flagged Rite Aid Mid-Atlantic shipments would be *de minimis*. As shown in **Exhibit 14**, under Dr. McCann's 3x trailing 12-month average method, and without applying the all-subsequent-shipments-are-tainted assumption, approximately **0.02%** of the total MMEs distributed into Cuyahoga and Summit Counties are flagged Rite Aid Mid-Atlantic shipments.[114] Furthermore, since Plaintiffs fail to show that any of Rite Aid Mid-Atlantic's orders led to diversion, the share that should be flagged for inclusion in other experts' damages calculations is zero.

[114] Depending on which of Dr. McCann's methodologies is applied, between 0.02 percent and 0.64 percent of the total MMEs distributed into Cuyahoga and Summit Counties are flagged Rite Aid Mid-Atlantic shipments. *See* backup materials.

Exhibit 14
Rite Aid Mid-Atlantic's Share of MMEs Distributed into Cuyahoga and Summit Counties, Total and Flagged by Dr. McCann's "Transaction Analysis"
2006-2014

		MMEs (in Millions)	% of Total MMEs
[A]	All MMEs distributed to dispensers in Cuyahoga and Summit Counties, excluding methadone, buprenorphine, and non-schedule II codeine	9,395	100.00%
[B]	Rite Aid Mid-Atlantic's hydrocodone MMEs distributed into Cuyahoga and Summit Counties	67	0.71%
[C]	Rite Aid Mid-Atlantic's hydrocodone MMEs flagged by Dr. McCann under 3x trailing 12 month average method	13	0.14%
[D]	Rite Aid Mid-Atlantic's hydrocodone MMEs flagged by Dr. McCann under 3x trailing 12 month average method, but without the all-subsequent-shipments-are-tainted assumption	2	0.02%

Notes and Sources:
[A] Based on backup materials to McCann Report and Master Drug Data Base (MDDB), Copyright 2019, *Clinical Drug Information*, LLC. "Dispensers," as defined by Dr. McCann, include "Buyers whose Business Activity suggests they dispense drugs to patients" (e.g., pharmacies, practitioners, and hospitals/clinics). Master Drug Data Base was used to identify non-schedule II codeine. If a codeine NDC did not appear in Master Drug Data Base, it was assumed to be non-schedule II.
[B] Based on Appendix 10 of McCann Report.
[C] Based on Appendix 10 of McCann Report. This method is with the all-subsequent-shipments-are-tainted assumption.
[D] Based on backup materials to McCann Report, but without the all-subsequent-shipments-are-tainted assumption.

E. Further evidence that Dr. McCann's "transaction analysis" is unreliable

83. To evaluate the validity of a methodology, an economist should perform robustness tests, which Dr. McCann has not done. In this section, I present the results of two very basic tests of his approach. In the first, I apply Dr. McCann's methodology to transactions for selected *non-opioid* drugs that do not have abuse potential and show that it flags large numbers of transactions as being suspicious. This analysis demonstrates that Dr. McCann's approach flags transactions as suspicious regardless of their potential for diversion. In the second, I show that his methodology fails to flag transactions to doctors who are known to have illegally distributed opioids. These tests are further evidence that Dr. McCann's analysis is incapable of distinguishing orders that were suspicious from those that were not.

1. Dr. McCann's analysis would also flag a large share of non-opioid transactions

84. A method for retrospectively flagging orders that will be identified as causing harm needs to be able to separate truly suspicious orders from orders that reflect expected variation in prescribing for non-suspicious reasons, especially if the method is not going to consider the information distributors like Rite Aid Mid-Atlantic gathered as part of its suspicious order monitoring. One established approach to testing this is to conduct a "falsification test" by applying the method to prescriptions for drugs that are not abused and therefore are not subject to the same potential for suspicious orders.[115] If applying the method flags a large number of orders for these non-controlled drugs, as it does for opioids, then that is evidence that Dr. McCann's method is not flagging truly suspicious orders. I routinely implement "falsification tests" such as these in my work, as do other academic economists, and have published on their importance in the *Journal of the American Medical Association*.[116]

85. To perform this test, I selected two drugs and one class of drugs, all of which are not controlled substances, and applied Dr. McCann's five methods for flagging orders to Ride Aid Mid-Atlantics shipments of these drugs to stores in Cuyahoga and Summit Counties.[117] The two drugs are metoprolol succinate (a drug used to treat angina [chest pain] and high blood pressure) and levothyroxine (a thyroid medicine used to treat hypothyroidism or prevent goiters, known by its brand name as Synthroid). The class of drugs is statins, which are used to lower cholesterol levels in the blood. These are very commonly prescribed medications.

86. As a first step, **Exhibit 15** compares the trends in total volume of these drugs distributed by Rite Aid Mid-Atlantic to Cuyahoga and Summit Countries to the volume of HCPs, using volume in number of shipments and dosage units.

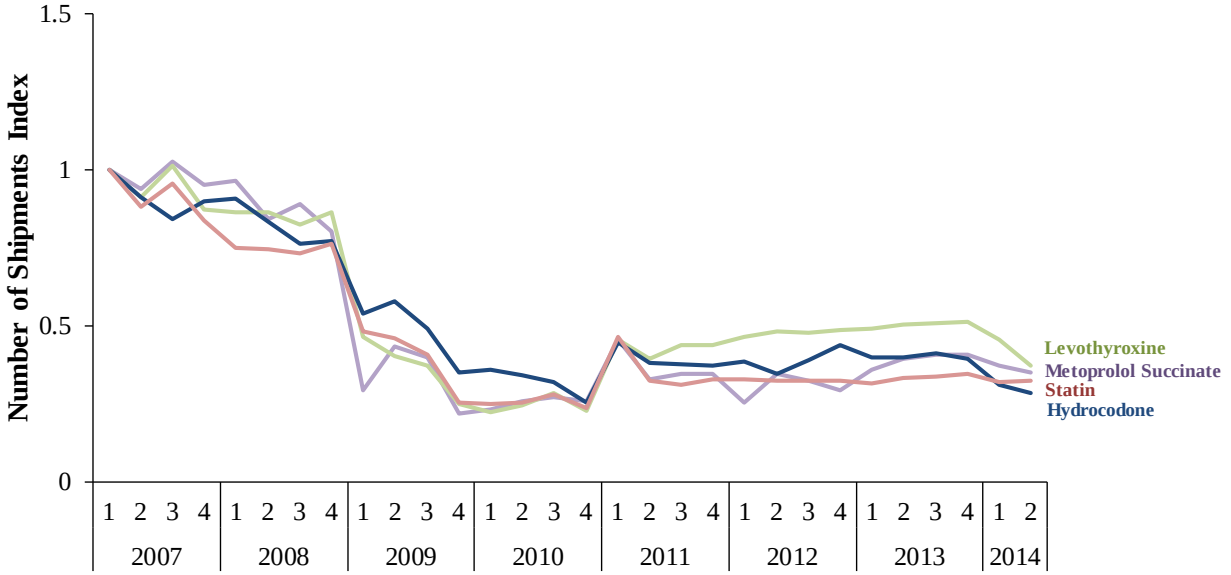
---

115 Jena, Anupam B., et al., "Mortality and Treatment Patterns among Patients Hospitalized With Acute Cardiovascular Conditions during Dates of National Cardiology Meetings," *JAMA Internal Medicine*, February 2015, Vol. 175, No. 2, pp. 237-244.

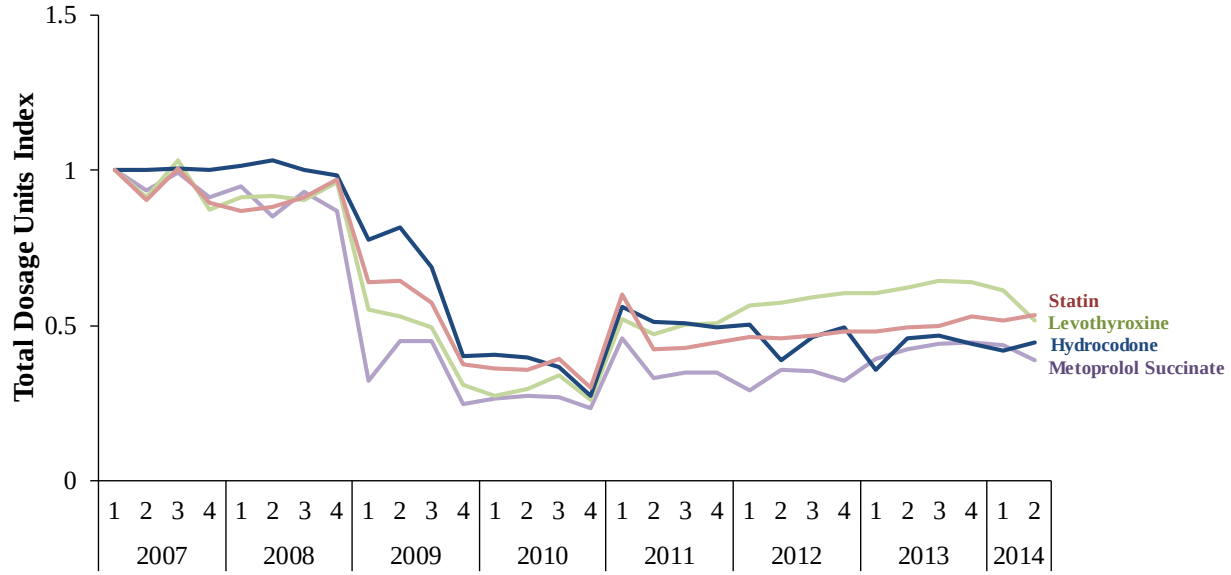
116 Prasad, Vinay, and Anupam B. Jena, "Prespecified Falsification End Points: Can They Validate True Observational Associations?" *JAMA*, Vol. 309, No. 3, January 2013, pp. 241-242.

117 Lipitor (a statin), Toprol XL (metoprolol succinate), and Synthroid (levothyroxine) were three of the four top pharmaceuticals sold in 2006 in units. I exclude Norvasc (amlodipine) because it has similar treatments for metoprolol succinate. The results for amlodipine are consistent. "Pharmaceutical Sales 2006," *Drugs.com*, available at https://www.drugs.com/top200_units_2006.html, accessed May 5, 2019.

Exhibit 15
Distribution of Opioids and Common Non-Controlled Drugs
From Rite Aid Mid-Atlantic to Cuyahoga and Summit Counties
Index of Number of Shipments



Index of Total Dosage Units



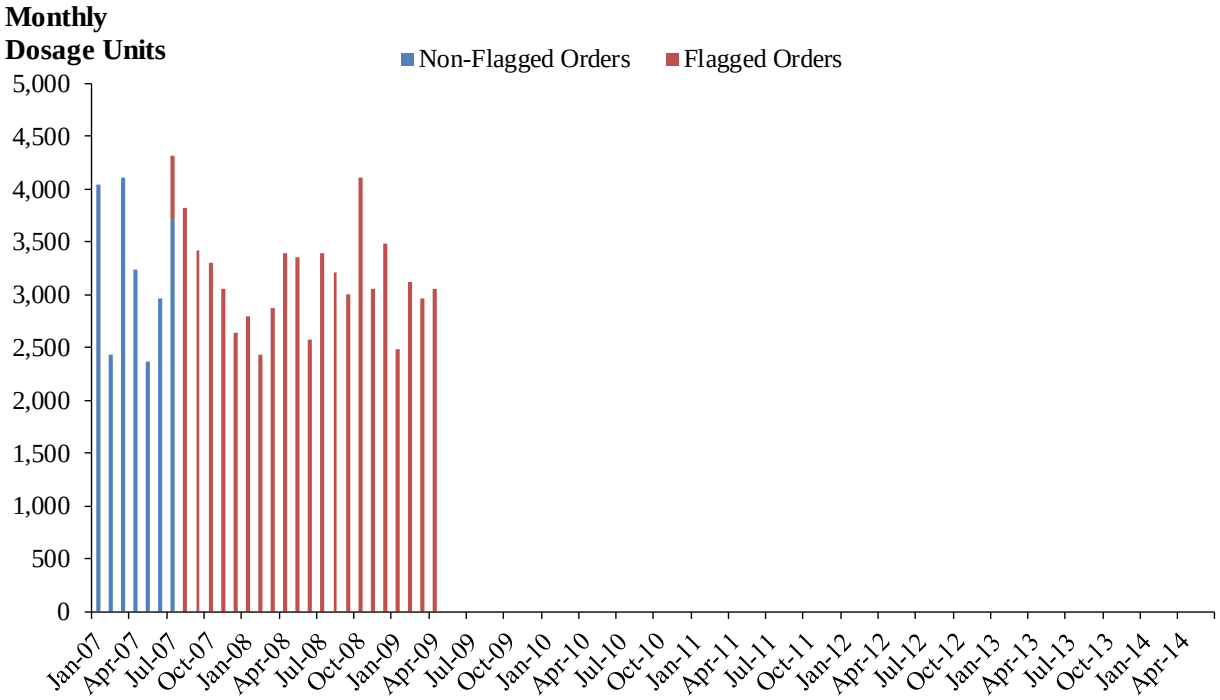
Notes:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.
[2] The Total Dosage Units (Number of Shipments) Index is calculated by dividing the total dosage units (the number of shipments) each quarter by the 2007 first quarter dosage units (number of shipments).

Sources:
[A] McCann Report (including backup materials).
[B] Rite_Aid_OMDL_0053882 (Rite Aid Mid-Atlantic data).
[C] Master Drug Data Base (MDDB), Copyright 2019, *Clinical Drug Information*, LLC.

Both charts suggest that distribution patterns of opioids and non-opioids to the Rite Aid stores in Cuyahoga County and Summit County are not materially different.[118]

87. As a second step, **Exhibit 16** shows an example of Dr. McCann's methods flagging large numbers of transactions for the selected non-controlled drugs at specific Rite Aid stores. Under Dr. McCann's first methodology, Mr. Rafalski's preferred methodology,[119] statins distributed to Rite Aid store #3152 are flagged at a similar rate as opioids, which is evidence that Dr. McCann's method is not flagging truly suspicious orders.

Exhibit 16
Distribution of Statins by Rite Aid Mid-Atlantic to Rite Aid Store #3152
Methodology: Maximum Monthly, Trailing Six-Month Threshold



Sources:
[A] McCann Report (including backup materials).
[B] Rite_Aid_OMDL_0053882 (Rite Aid Mid-Atlantic data).
[C] Master Drug Data Base (MDDB), Copyright 2019, *Clinical Drug Information*, LLC.

88. Finally, **Exhibit 17** calculates the share of transactions flagged for each of the selected non-controlled drugs using Dr. McCann's first approach.

[118] As a robustness check, I also conduct a similar analysis at the store-level for each of Rite Aid's 43 stores in Cuyahoga County and Summit County. These charts can be found in Appendix E.
[119] Rafalski Report, p. 46.

Exhibit 17
Flagged Rite Aid Mid-Atlantic Shipments of Selected Non-Controlled Drugs
Methodology: Maximum Monthly, Trailing Six-Month Threshold

	Cuyahoga County	Summit County
Controlled Drug (Jan. 2006 - Sept. 2014)		
Hydrocodone	87%	88%
Non-Controlled Drugs (Jan. 2007 - Jun. 2014)		
Metoprolol Succinate	71%	76%
Levothyroxine	75%	78%
Statin	76%	80%

Notes:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.
[2] Flagged percentages for hydrocodone are based on ARCOS data in backup materials to McCann Report, while the flagged percentages for non-controlled drugs are based on Rite_Aid_OMDL_0053882 (Rite Aid Mid-Atlantic data).

Sources:
[A] McCann Report (including backup materials).
[B] Rite_Aid_OMDL_0053882 (Rite Aid Mid-Atlantic data).
[C] Master Drug Data Base (MDDB), Copyright 2019, *Clinical Drug Information*, LLC.

89. Applying Dr. McCann's analysis to non-opioid transactions provides strong evidence that his methodology is not identifying truly suspicious orders, but rather is falsely flagging orders due to monthly fluctuations in ordering patterns that are common across other drugs.

2. Dr. McCann's analysis fails to flag transactions to doctors who have illegally distributed opioids at higher rates than actual pharmacies

90. Ultimately, for the purposes of evaluating harm caused by the distribution of opioid products, Dr. McCann's transaction analysis is only useful to the extent that it can identify suspicious orders that lead to diversion. But a method that cannot discern known illegitimate orders from any other order provides no value. This is exactly what I observe with Dr. McCann's methods.

91. Because Dr. McCann only analyzes transactions to pharmacies, he fails to flag *any* transactions for direct shipments to doctors who have illegally distributed opioids to patients.[120] One such former physician, Cynthia Cadet, was convicted of "conspiracy to commit money laundering" related to her dispensing of oxycodone and other controlled substances that resulted in the

[120] Dr. McCann states that his transaction analysis is for transactions by a "Distributor to a Pharmacy." McCann Report, ¶ 131. Dr. McCann provides no rationale for limiting his analysis in his report to pharmacies.

deaths of seven individuals.[121] Ms. Cadet received shipments of oxycodone from Medical Arts, among other distributors.[122]

92. If one were to apply Dr. McCann's threshold analysis to Medical Arts' shipments to Ms. Cadet, the results flag some, but not all, transactions under certain methodologies. As seen in **Exhibit 18** below, under Dr. McCann's first methodology, only 56 percent of transactions are flagged. These results can be compared to Dr. McCann's analysis of Rite Aid Mid-Atlantic distribution to Rite Aid Store #3228. If one were to simply look at these results from Dr. McCann's methodologies, it would be hard to discern which set of shipments was to a convicted criminal serving jail time related to her illegal distribution of opioids that resulted in patient deaths. The fact that Dr. McCann's methodologies flag the Rite Aid transactions at *higher* rates than those for the shipments to Ms. Cadet demonstrates why Dr. McCann's method is effectively useless for purposes of evaluating harm caused by distributors' actions.

Exhibit 18
Comparison of Percentage of Flagged Oxycodone/Hydrocodone Transactions for Cynthia Cadet vs. Rite Aid #3228
Methodology: Maximum Monthly, Trailing 6 Month
Practitioner/Pharmacy Specific Threshold

	# of Flagged Transactions	Total # of Transactions	% of Flagged Transactions
Oxycodone Shipments from Medical Arts to Cynthia Cadet (Dec. 2008 - Feb. 2010)	35	62	56%
Hydrocodone Shipments from Rite Aid Mid-Atlantic to Rite Aid #3228 (Jan. 2006 - Apr. 2008)	31	39	79%

Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Sources:
[A] McCann Report (including backup materials).

[121] Department of Justice, "Jury Convicts Two Doctors Of Conspiracy To Commit Money Laundering Resulting From Pill Mill Operation In Broward And Palm Beach Counties," 2013, available at https://www.justice.gov/usao-sdfl/pr/jury-convicts-two-doctors-conspiracy-commit-money-laundering-resulting-pill-mill, accessed on May 8, 2019.
[122] ARCOS Data Files.

93. Dr. McCann's flagging methodology is not even effective for identifying transactions to known "pill mill" pharmacies. Bevis Vanterpool, the sole pharmacist of TraceMark Pharmacy, which he owned and operated, was convicted of "conspiring to distribute oxycodone" after accepting and filling nearly 5,000 fraudulent prescriptions.[123] As seen in **Exhibit 19** below, applying Dr. McCann's first methodology results in a flagging of only 48 percent of transactions from Value Drug to this known "pill mill." Continuing with the example from above, Dr. McCann's methodology flags transactions from Value Drug to TraceMark at substantially lower rates than transactions from Rite Aid Mid-Atlantic to Rite Aid pharmacy #3228 (79 percent). This again demonstrates that Dr. McCann's methodology cannot discern between transactions to illegitimate pharmacies and those to legitimate chain pharmacies.

Exhibit 19
Comparison of Percentage of Flagged Hydrocodone Transactions for TraceMark Pharmacy vs. Rite Aid #3228
Methodology: Maximum Monthly Trailing 6 Month Pharmacy Specific Threshold

	# of Flagged Transactions	Total # of Transactions	% of Flagged Transactions
Hydrocodone Shipments from Value Drug Co to TraceMark (April 2010 - Feb. 2011)	95	197	48%
Hydrocodone Shipments from Rite Aid Mid-Atlantic to Rite Aid #3228 (Jan. 2006 - Apr. 2008)	31	39	79%

Note:
[1] All Rite Aid Mid-Atlantic hydrocodone transactions are HCPs.

Source:
[A] McCann Report (including backup materials).

[123] FBI, U.S. Attorney's Office, Eastern District of Pennsylvania, "Pharmacist's Drug Conviction Results in 63 Month Prison Term," May 26, 2015, available at https://www.fbi.gov/contact-us/field-offices/philadelphia/news/press-releases/pharmacists-drug-conviction-results-in-63-month-prison-term, accessed May 9, 2019.

F. Dr. McCann's analysis of "excessive shipments" is arbitrary and without support

94. Dr. McCann presents an analysis that purportedly estimates the shipments that exceeded the "medically necessary" opioid shipment level.[124] To estimate excessive shipments, he constructs two "possible" baselines: a 1997 to 2018 interpolated baseline and a 1997 constant baseline. He presents the first as an upper bound and the latter as a lower bound.[125] Both baselines are unsupported and arbitrary, as Dr. McCann fails to explain or justify why either measure represents the "medically necessary" level of opioid shipments. From both an economic and medical perspective, any analysis using "baseline" comparisons must account for differences in other relevant factors that could explain the observed deviations from the baseline. For example, the rate of adoption for the medical products in question must be considered in this type of analysis, as it is possible that at the time period chosen for the "baseline," the medical innovation was still in the process of being adopted by healthcare practitioners.[126]

95. Based on this flawed analysis, Dr. McCann claims that the excessive shipment results validate his analysis of identifying and flagging transactions. Specifically, he claims that his "estimates of the percentage excessive shipments into Ohio in Table 45 - which average 71.3% - are a useful frame of reference for evaluating the transactions flagged by the methods in the previous subsections."[127] He further claims that "the implication that more than 70% of opioids shipped into Ohio were excessive, supports my identification of transactions."[128] It does not make sense for Dr. McCann to use his excessive shipment analysis in support of his transaction analysis, as both analyses are arbitrary and unsupported. In this sense, the entire exercise is tautological – Dr. McCann's results from the two analyses are consistent with each other because he imposes the same flawed assumptions that drive his results. Namely, he falsely asserts that observed opioid use early on must be representative of the true medical need for these products and any growth in opioid shipments is suspicious.

---

124 McCann Report, Section X.
125 *Id.*, ¶¶ 155-156.
126 *See* Rogers, Everett M., *Diffusion of Innovations*, (Fifth Edition), Free Press, 2003, pp. 64-68.
127 McCann Report, ¶ 160.
128 *Id*.

VI. PLAINTIFFS PROVIDE NO ASSESSMENT OF HARM RESULTING FROM RITE AID MID-ATLANTIC'S ROLE IN DISTRIBUTING HYDROCODONE COMBINATION PRODUCTS

96. While Plaintiffs' experts provide a variety of opinions related to the actions of distributor defendants, none of the experts show a causal relationship between Rite Aid Mid-Atlantic's alleged failure to implement diversion controls and actual harm. My analysis of this issue stems from the critical need to separate two forms of inappropriate opioid use: outright diversion versus routine overprescribing of opioids. With regards to the former, Plaintiffs' experts, specifically Dr. McCann, do not convincingly demonstrate what proportion of opioids could reasonably be considered to reflect diversion nor do they consider the steps Rite Mid-Atlantic took in its own suspicious order monitoring system. With regards to routine overprescribing, this likely contributes to many of the opioid prescriptions present in the ARCOS data, but this opioid utilization stems from a failure in provider decision-making and prescribing rather than a failure of pharmacy or distributor oversight.

97. Based on my review of the expert reports filed by 19 Plaintiff experts in this matter, I have not seen any analysis demonstrating that Rite Aid Mid-Atlantic failed to maintain effective controls against diversion, nor have I seen any analysis demonstrating specific harm resulting from Rite Aid Mid-Atlantic's distribution of HCPs to Rite Aid pharmacies in Cuyahoga and Summit Counties. Appendix D to this report catalogs the Plaintiffs' expert reports submitted to date, and indicates specific references to "Rite Aid." Only 8 of the 19 Plaintiff experts include any specific reference to a Rite Aid entity and only Dr. McCann evaluates Rite Aid Mid-Atlantic.[129]

A. Plaintiffs' experts provide no analysis demonstrating that Rite Aid Mid-Atlantic failed to maintain effective controls against diversion

98. I have seen no analysis from Plaintiffs' experts demonstrating that Rite Aid Mid-Atlantic failed to maintain effective controls against diversion. A number of Plaintiffs' experts address whether the distributor Defendants complied with the statutory and regulatory duties to

[129] While Dr. Egilman mentions "Rite-Aid" as a wholesaler, his opinion is limited to "'Venture' members had agreements with wholesalers." *See* Appendix D and Exhibit B.477 to the Report of David S. Egilman MD, MPH, March 25, 2019.

maintain effective controls against diversion and report suspicious orders.[130] Specifically, Mr. Rafalski and Dr. Whitelaw focus on these issues most directly. However, none of Plaintiffs' experts provide any assessment of Rite Aid Mid-Atlantic's systems to monitor and control distribution of its controlled substances, which I describe above in Section IV.A. While each Plaintiff expert provides descriptions of other retailer distributor defendants' actions around monitoring controlled substances, there is no discussion by any of these experts in their respective reports regarding Rite Aid Mid-Atlantic and its efforts.

99. For instance, in his report Mr. Rafalski discusses whether distributor Defendants complied with the statutory and regulatory duties to maintain effective controls to prevent diversion and report suspicious orders.[131] Mr. Rafalski determines that six distributors failed to comply with these statutory and regulatory duties, but Rite Aid Mid-Atlantic is not one of them.[132]

100. Similarly, Dr. Whitelaw evaluates the compliance controls employed by "G2" distributors, which are defined as distributors that "have a standard business model that involves embedding distribution operations within a large, national pharmacy chain that supplied only its own pharmacies with opioid products."[133] Although Rite Aid Mid-Atlantic fits this description, Dr. Whitelaw did not evaluate Rite Aid Mid-Atlantic.[134]

101. In fact, based on their respective materials considered lists, none of these experts even considered Rite Aid Mid-Atlantic documents, deposition testimony, or interrogatory responses related to the company's order monitoring practices. In this sense, any conclusion made by these experts pertaining to Rite Aid Mid-Atlantic is baseless.

---

130 Rafalski Report, p. 46 ("…each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders…"); Whitelaw Report, p. 46 ("…[retailer distributor defendants] made only token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market and then only when the DEA directed them to.").

131 Rafalski Report, Section IV.

132 *Id*.

133 Whitelaw Report, p. 3.

134 *Id*.

B. Plaintiffs' experts provide no assessment of harm resulting from Rite Aid Mid-Atlantic's distribution of HCPs to its network of pharmacies

102. Additionally, I have seen no assessment from Plaintiffs regarding any actual economic harm (i.e., additional costs incurred) caused by Rite Aid Mid-Atlantic's distribution of HCPs into its network of pharmacies in Cuyahoga and Summit Counties. None of Plaintiffs' experts present evidence demonstrating harm caused by Rite Aid Mid-Atlantic's distribution of HCPs into Cuyahoga and Summit Counties. For example:

- Dr. Cutler provides an analysis in his report that attempts to attribute harm due to the defendant distributors' actions; however, his analysis of the share of opioid harms due to distributors' behavior is done in the aggregate, presumably across all distributor defendants.[135] As such, this analysis provides no assessment of harm attributable to Rite Aid Mid-Atlantic specifically.[136] In addition, Dr. Cutler's analysis is entirely dependent on estimates of the share of excessive opioid shipments that distributors failed to identify.[137] To the extent the underlying source data used by Dr. Cutler as an input is Dr. McCann's transaction analysis, then Dr. Cutler's resulting estimates of harm are incorrect as it is premised on Dr. McCann's deeply flawed analysis.[138]

- As discussed above, Dr. McCann presents a "transaction analysis" and presents an analysis of excessive shipments, but beyond "flagging" transactions he provides no analysis showing which Rite Aid Mid-Atlantic shipments were used in an illicit fashion or resulted in any harm.[139]

---

135 Cutler Report, ¶ 9.

136 Furthermore, Dr. Cutler admits that the analysis of harm that he presents in his report does not uniquely attribute harm resulting from actions by any individual type of defendant, stating that there is "no unique or economically 'correct' allocation of liability" for the harm that could have been avoided if each party had met its legal obligations. *Id.*, Appendix III.J, ¶ 3; ¶ 31 ("In some circumstances when multiple parties contribute to the same indivisible harms, it is unlikely that a unique attribution of harm to each contributing part is possible.").

137 *Id.*, Appendix III.J, ¶ 4. Dr. Cutler cautions that his analysis is simply an "example of how this analysis can be applied if appropriate data become available to estimate the share of prescription opioid shipments that reflect distributor misconduct." *Id.*, Appendix III.J, ¶ 5. Dr. Cutler also notes that these data were provided by counsel and will be set forth in reports to be disclosed on April 15, 2019. *Id.*, Appendix III.J, ¶ 6. I have reviewed the reports disclosed on April 15, 2019 by Plaintiffs, and have been unable to confirm or verify the source of the data Dr. Cutler presents in his Table J.1.

138 *See* Section V above.

139 McCann Report, ¶ 130.

- Dr. Rosenthal, Dr. Schumacher, Dr. Kessler, and Ms. Keller focus their reports exclusively on the conduct of manufacturer defendants.[140] None of these experts address Rite Aid Mid-Atlantic's behavior.

- Dr. Gruber opines that there is a causal relationship between defendants' (including distributors) shipments of prescription opioids and opioid misuse and mortality.[141] Certainly, one cannot dispute the morbidity and mortality associated with opioid use, but the critical question is not whether opioids are dangerous – they are – but whether, in the case of Rite Aid Mid-Atlantic, any opioid-related adverse outcomes stem from diversion of opioids enabled by this distributor or instead stem from the routine but inappropriate and dangerous use of opioids that I have described throughout my report. Dr. Gruber does not analyze Rite Aid Mid-Atlantic's role in distributing opioid products, and his opinions are not linked to any diversions from suspicious orders that were shipped by Rite Aid Mid-Atlantic.

- Dr. McGuire estimates damages (i.e., the cost consequences of harms to the government due to the defendants' actions) based on the analyses presented in Dr. Rosenthal's, Dr. Cutler's, and Dr. Gruber's reports, and does not present any additional, independent analyses related to Rite Aid Mid-Atlantic's behavior.[142]

- Dr. Perri opines that defendants' (including distributors) marketing practices expanded the market for prescription opioids.[143] However, he provides no analysis of Rite Aid

---

[140] Rosenthal Report, ¶ 7 ("In this Report, I refer to the manufacturers' deceptive marketing strategy and tactics as 'manufacturer misconduct.' This report does not address non-marketing misconduct."); Schumacher Report, footnote 1 ("'Defendants' as used herein refers to the Defendant manufacturers of branded and generic opioid products in the actions brought by Plaintiffs Cuyahoga County and Summit County…"); Kessler Report, ¶ 12 ("I have also been asked to review the discovery records of specified defendant opioid manufacturers for the purpose of formulating an opinion as to whether any one or more of those manufacturers departed from accepted drug regulatory standards and, if so, to describe how."); Keller Report, ¶ 22 ("This report focuses specifically and exclusively on manufacturers' anti-diversion and suspicious order monitoring programs.").

[141] Gruber Report, ¶ 16. Dr. Gruber's opinion, in part, relies on an assumption that variation in per capita shipments across counties with similar populations indicates that shipments were suspicious. He ignores the fact that even within a county, variation is routine, as many factors lead to variation in per capita shipments across counties for which he does not control (e.g., presence of a large hospital in that county, number of pharmacies in the county, etc.). *Id.*, ¶ 14.

[142] McGuire Report, ¶¶ 6, 14-19.

[143] Expert Report of Matthew Perri III, BS Pharm, PhD, RPh, March 25, 2019, pp. 8-9.

Mid-Atlantic's specific role in marketing opioids, and no analysis of harm attributable to Rite Aid Mid-Atlantic's behavior.

VII. PLAINTIFFS' CHARACTERIZATION OF RITE AID MID-ATLANTIC'S ROLE IN THE DISTRIBUTION OF OPIOID PRODUCTS FAILS TO CONSIDER THE ROLE OF PHYSICIANS

103. A number of Plaintiffs' experts comment on the role of physicians and prescribers in regards to the distribution of opioid products.[144] These experts, however, fail to connect how medical professional prescribing relates to Rite Aid Mid-Atlantic's distribution of opioids. To the extent that Plaintiffs contend that Rite Aid's distribution facilities were incentivized to prioritize "sales above safety," promote opioid product sales, and effectively increase prescription opioid demand, the contention is misguided. Specifically, it trivializes the critical role that physicians play in driving pharmaceutical demand, changes in medical knowledge over this time period, and changes in regulatory efforts to monitor opioid use.[145] As such, any characterization by Plaintiffs that Rite Aid Mid-Atlantic was encouraging opioid product sales and thereby increasing demand for the products while intentionally ignoring patient safety is incorrect. In my opinion, there was no substantial incentive for Rite Aid Mid-Atlantic to promote opioid sales. Consistent with this, I've seen nothing to suggest that Ride Aid Mid-Atlantic attempted to promote opioid sales, or that Rite Aid Mid-Atlantic's behavior affected prescribers.

104. At a high level, Rite Aid Mid-Atlantic's distribution volumes are derived from pharmacy orders which are driven by prescriptions written by *physicians or other healthcare providers*. The importance of the prescriber in driving demand for opioids is recognized by Plaintiffs.[146] Given the importance of physicians in driving the quantities of opioid products that Rite Aid Mid-Atlantic distributes, it is essential to understand the relationship between physicians and in turn pharmacists as it pertains to ordering and dispensing of prescription opioids.

---

144 *See, e.g.*, Rosenthal Report, ¶¶ 14-15; ¶ 2; Expert Report of David S. Egilman, March 25, 2019, p. 52.

145 In addition to physicians, other healthcare providers (e.g., Registered Nurses) may have prescribing authority for prescription opioids. For purposes of this report, I use the term "physicians" to characterize all healthcare providers with prescribing authority.

146 Rosenthal Report, ¶¶ 12-17 (describing pharmaceutical demand and highlighting the importance of physicians and insurance providers, as well as "information problems" that both physicians and patients face when selecting a pharmaceutical product).

105. The traditional role of the physician in treating a patient is to diagnose disease and recommend appropriate treatment that is based on a multitude of factors, including patient preferences, expected efficacy of treatment, tolerability of a treatment's side effects, physician experience with prescribing a particular treatment, recommendations outlined in professional guidelines, and cost, among other factors. In the case of opioids, physicians must assess pain related to underlying disease (or in the case of procedures, post-procedure pain) and assess whether opioids may be suitable for the short-term relief of pain and if so the dosage and duration of treatment. The ultimate treatment that is chosen for a patient is a decision that is made by a physician.

106. It is well known from the existing scientific literature that physicians are quite variable in how they manage pain and how heavily they rely on opioids to treat pain. For example, in my own research published in the *New England Journal of Medicine*, I showed that among patients who are opioid-naïve and present for acute care to an emergency department, the probability of being prescribed an opioid at the time of emergency department discharge varies by nearly 3-fold *in the same emergency department* depending solely on the physician treating the patient.[147] Other studies have demonstrated a similar degree of variation in opioid prescribing practices across physicians.[148] These research findings explain, in part, the variability in opioid distribution that is observed across pharmacies as this physician behavior ultimately drives the distribution of prescription opioids to pharmacies.

107. My own research has also shown that among patients who are admitted to the hospital without a prior opioid use history, there is wide variation between hospitals in the likelihood that a patient will be discharged with an opioid prescription from the hospital.[149] For instance, in the first national Medicare analysis of opioid prescribing at hospital discharge, I found that among Medicare beneficiaries hospitalized in 2011, 15 percent were prescribed an opioid after discharge for a general medical condition and of these patients, 43 percent remained on an

---

147 Barnett, Michael L., et al., "Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use," *The New England Journal of Medicine*, Vol. 376, No. 7, February 2017, pp. 663-673 (hereafter, "Barnett, et al. (2017)").

148 Ly, Dan P., "Differences Within Practices in Opioid-Prescribing Patterns of Orthopedic Surgeons and in Subsequent Rates of Chronic Opioid Use, 2012-2014," *Journal of General Internal Medicine*, Vol. 34, No. 4, April 2019, pp. 529-531.

149 Jena, et al. (2016).

opioid after 90 days.[150] There was a nearly two-fold variation across these hospitals in opioid prescribing rates.[151] Other studies, including those outside of the United States, have found similar patterns. For example, studies have found that among patients undergoing major elective surgery, nearly 50 percent fill an opioid prescription after discharge and 3 percent to 9 percent of patients receiving surgical follow-up continue to receive opioids after 90 days.[152] My interpretation of these studies is that they highlight the critical role that physician prescribing practices – in particular, variation in those practices across individual physicians – play in explaining why some patients are treated with opioids and others are not, and thus why demand for opioids varies. *These differences are generated by differences in how physicians prescribe opioids, not on policies or practices employed by distributors or pharmacists.*

108. In contrast to the physician, the pharmacist has traditionally been responsible for the accurate processing of prescription orders, and assuring that prescriptions were properly filled. So while pharmacists clearly play an important part of the distribution and delivery of medication to patients, the prescription writing responsibility (i.e., the determination of which medication can be used to appropriately treat a patient) is squarely with the physician. In this sense, it would be uncommon for pharmacists to refuse to fill a prescription for a physician for certain drugs unless there is clear indication that the medication would be harmful to the patient. In my own practice, I have experience with pharmacists and they serve a critical role in identifying drug side effects, potential drug-drug interactions, and modifying dosing based on weight or liver/kidney function. But it would be highly unlikely for a pharmacist to disagree with a clinical diagnosis and would be inappropriate for a pharmacist to refuse to dispense a physician-prescribed medication without first conferring with the prescribing physician.[153] In particular, barring a clear indication that a medication is inappropriate for a patient, which

---

150 *Id*.

151 *Id.*

152 Clarke, Hance, et al., "Rates and Risk Factors for Prolonged Opioid Use after Major Surgery: Population Based Cohort Study," *BMJ*, 348:g1251, February 2014; Jiang, Xueying, et al., "Chronic Opioid Usage in Surgical Patients in a Large Academic Center," *Annals of Surgery*, Vol. 265, No. 4, April 2017, pp. 722–727.

153 For example, if a physician provides a diagnosis of pneumonia for a patient and recommends treatment with a specific antibiotic to treat a particular bacterial pathogen, the role of the pharmacist would not be to a) determine whether the patient in fact had pneumonia or b) decide what is the appropriate antibiotic that targets the suspected pathogen. Rather the pharmacist would be most helpful in c) stating that given the patient's kidney clearance, a lower dose of the suggested antibiotic might suffice. In this case, the pharmacist would nearly always confirm with the ordering physician that a dose reduction is mutually agreed upon, rather than unilaterally change the prescribed dosage.

requires a clinical assessment that is most often allocated to the treating physician, pharmacists typically dispense the medication prescribed by the treating physician.

109. Indeed, the refusal of a pharmacist to supply a patient with a written prescription would be cause for concern unless strongly clinically justified. For example, patients with sickle cell disease – a disease in which red blood cells become deformed and cause obstruction in small blood vessels of the body – frequently experience severe pain crises due to their underlying disease. Concerns have been raised that African American patients with this disease are undertreated for pain despite in many instances having bone pain that feels similar to an acute fracture.[154] If pharmacists were to refuse dispensing opioids to these patients because of race-based stereotyped concerns of opioid misuse, that would be cause for significant concern.[155] In addition to this specific example, it is also important to recognize that physicians have broadly noted that denial of appropriate opioid prescriptions to patients for the treatment of pain may lead to worse outcomes for patients.[156] Consistent with these positions, any restrictions put in place by pharmacies that result in denying opioid prescriptions to patients must be carefully weighed, as the consequences can be substantial. Furthermore, it could be harmful to the doctor-patient relationship for pharmacies to second-guess decisions within the range of reasonable medical judgment.

110. This is not to say that pharmacists have no role in identifying unsafe prescriptions. Clearly, they do, but that role naturally focuses on instances where there is clear harm being posed to a patient or where there is evidence of patient or prescriber diversion of opioids. Beyond these instances, pharmacists have a limited, if any, role in denying prescription opioids written by a treating physician.

---

[154] Haywood Jr., Carlton, et al., "Perceived Discrimination in Health Care is Associated with a Greater Burden of Pain in Sickle Cell Disease," *Journal of Pain Symptom Management*, Vol. 48, No. 5, November 2014, pp. 934-943.

[155] Bouscaren, Durrie, "Suspicions in the ER: a consequence of the opioid epidemic," *WHYY*, January 9, 2017, available at https://whyy.org/segments/suspicions-in-the-er-a-consequence-of-the-opioid-epidemic/, accessed May 9, 2019.

[156] *See* Kroenke, Kurt and Andrea Cheville, "Management of Chronic Pain in the Aftermath of the Opioid Backlash," *JAMA*, Vol. 317, No. 23, June 2017, pp. 2365 - 2366; Alford, Daniel P., "Opioid Prescribing for Chronic Pain - Achieving the Right Balance through Education," *The New England Journal of Medicine*, Vol. 374, No. 4, January 2016, pp. 301-303.

111. The ability of a pharmacist to adequately determine whether a physician's opioid prescription for a particular patient is appropriate is extremely challenging, requiring a substantial amount of information about the patient and the patient's medical history, not to mention formal medical training. Studies demonstrating variation in physician and hospital prescribing of opioids mean that evaluating prescribing trends and practices is extremely difficult. In these studies, the observed variation in opioid prescribing, which was large, was due to differences in prescribing tendencies across physicians and across hospital systems, and had nothing to do with the pharmacies in which prescriptions were filled. Moreover, differences between physicians in their short-term prescribing habits had implications for long-term prescription opioid use by patients. For example, in my *New England Journal of Medicine* study described above, patients who were initially treated by a high-intensity opioid prescriber in the emergency department setting were nearly 30 percent more likely to be taking a prescription opioid *one year later*, compared to patients who were, by chance, initially treated by a low-intensity prescriber.[157] This, and related studies, highlight the important role of *routine* physician prescribing variation on not only short-term but long-term prescription opioid use by patients.[158]

112. Furthermore, the ability of individuals involved in the distribution chain for prescription opioid products to assess the appropriateness of a patient's opioid prescription is hindered by the continuously evolving state of clinical practice. This notion, described in the literature as "medical reversals," can mean that even individuals that believed they were complying with medical best practices in filling prescriptions at a point in time, could have been, in retrospect, failing to do so.[159] It is well known that in the nascent stages of the growth in opioid use in this country, physicians and other health care providers focused heavily on the under-treatment of pain and increasingly relied on opioids for the treatment of pain, a trend that reversed with

---

157 Barnett, et al. (2017), p. 667.

158 For example, Jena, et al. (2016) finds substantial variation across hospitals in new opioid use after hospitalization of Medicare beneficiaries. Similarly, another study reports wide variation in the number of opioid pills prescribed to patients undergoing the same operation. Hill, Maureen V., et al., "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," *Annals of Surgery*, Vol. 265, No. 4, April 2017, pp. 709-714.

159 *See Prasad*, Vinay, "The Frequency of Medical Reversal," *Archives of Internal Medicine*, Vol. 171, No. 18, October 2011, pp. 1675-1676.

the generation of mounting clinical evidence on the short- and long-term adverse effects of opioid use.[160] This reversal in medical knowledge means that individuals involved in the distribution chain for prescription opioid products early in the period of growing opioid use in this country were likely uninformed about the major adverse impacts of prescription opioid use. At least for a period of time early in the opioid epidemic (e.g., prior to 2008), it would be arguably difficult to show that these individuals involved in the distribution chain were "turning a blind eye" in these situations - they may simply have been using the best information available to them at the moment.

113. Indeed, the information available to physicians on the degree of potential opioid misuse by patients also changed substantially in Ohio over the past two decades, largely due to important state regulatory efforts to monitor suspicious opioid use. In 2006, Ohio instituted a Prescription Drug Monitoring Program (PDMP), known as the Ohio Automated Rx Reporting System (OARRS), to "address the growing misuse and diversion of prescription drugs."[161] OARRS is a database that contains prescription information for controlled substances dispensed by pharmacies and prescribers in Ohio.[162] It can be used to identify patients who obtain controlled substances from different physicians, or to identify doctors with inappropriate prescribing and dispensing trends.[163]

114. Other states have also implemented PDMPs, with each state varying in the degree of prescribing physician and pharmacist involvement required before an opioid prescription was dispensed to a patient. For example, in some states, including Massachusetts, when prescribing an opioid product to a patient, physicians were at various points required to access a centralized database of prescription opioid use to assess any inappropriate opioid use by the patient. By 2014, 22 of the 49 states that implemented PDMPs required that prescribers search the system

---

[160] For example, one of the authors of an early academic article allegedly used to inappropriately promote that opioids were rarely addictive, Dr. Russel Potenoy, has said more recently in 2012 that information on opioid use has evolved, and that his early teachings were misinformed: "We didn't know then what we know now." Catan, Thomas and Evan Perez, "A Pain-Drug Champion Has Second Thoughts," *The Wall Street Journal*, December 17, 2012.

[161] State of Ohio Board of Pharmacy, "Ohio Automated Rx Reporting System," available at https://www.ohiopmp.gov/About.aspx, accessed May 5, 2019.

[162] OARSS also includes prescription information for one non-controlled substance, gabapentin. *Id.*

[163] *Id*.

prior to prescribing controlled substances that have potential for abuse or dependence.[164] As of January 2019, 43 states require PDMP enrollment and 44 U.S. states or territories require PDMP query by prescribers or dispensers.[165]

115. In summary, any characterization by Plaintiffs that Rite Aid Mid-Atlantic was encouraging opioid product sales and thereby increasing demand for the products while intentionally ignoring patient safety is incorrect. These arguments trivialize the critical role that physicians play in driving pharmaceutical demand, and changes in medical knowledge over this time period. To be clear, these arguments sidestep the important role of health care providers in potentially contributing to the opioid epidemic through the unintended routine prescribing of opioids that we have now come to clearly understand was clinically unfounded in many circumstances.

Anupam B. Jena, M.D., Ph.D.

May 10, 2019

[164] Haffajee, et al. (2015).

[165] Prescription Drug Monitoring Program Training and Technical Assistance Center, "PDMP Mandatory Enrollment of Prescribers and Dispensers," available at http://www.pdmpassist.org/pdf/Mandatory_Enrollment_20190115.pdf, accessed May 5, 2019; and Prescription Drug Monitoring Program Training and Technical Assistance Center, "PDMP Mandatory Query by Prescribers and Dispensers," available at http://www.pdmpassist.org/pdf/Mandatory_Query_20190115.pdf, accessed May 5, 2019.